Surgical Instrument Serv. Co. v. *Intuitive Surgical, Inc.*
No. 3:21-cv-03496-AMO (N.D. Cal.)

MATERIALS FOR JUROR 5

Volume 6

Pages 1059 - 1212

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

Before The Honorable Araceli Martínez-Olguín

SURGICAL INSTRUMENT SERVICE COMPANY, INC., et al.,	)	
Plaintiffs,	)	
VS.	)	**NO. C 21-03496-AMO**
INTUITIVE SURGICAL, INC.,	)	
Defendant.	)	
AND RELATED COUNTERCLAIMS.	)	

San Francisco, California
Monday, January 13, 2025

TRANSCRIPT OF PROCEEDINGS

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I N D E X

Monday, January 13, 2025 - Volume 6

E X H I B I T S

Monday - January 13, 2025 7:57 a.m.

P R O C E E D I N G S

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[redacted]

(The jury enters the courtroom.)

(Proceedings were heard in the presence of the jury.)

(Keith Johson steps forward to resume the stand.)

KEITH JOHNSON,

called as a witness for the Plaintiffs, having been previously duly sworn, testified further as follows:

THE COURT: You may be seated.

REDIRECT EXAMINATION

BY MR. McCAULLEY:

Q. Mr. Johnson, welcome back.

A. Good morning.

Q. I'm a little more understandable hopefully today.

Do you remember last week you testified that you had a number of meetings with hospitals and healthcare providers about the EndoWrist repair service?

A. Yes.

Q. Is there any doubt -- you faced a lot of cross-examination. Is there any doubt that those meetings took place in your mind?

A. Not at all.

[redacted]

BY MR. McCAULLEY:

Q. Did the lack of documentation shake your confidence at all that those meetings took place?

A. No.

Q. You left the stand on Friday; correct?

A. Yes.

Q. Where did you go?

A. Home.

Q. Other than to tell me when your flight was landing, have we had any communication since then?

A. No.

Q. I'd like to ask you about Scripps Health. Are you familiar with Scripps Health?

A. In San Diego? Yes.

Q. Did you have any meetings with Scripps Health about the EndoWrist program?

A. I did have, yes.

Q. Who would you have meetings with?

A. I can picture his face. I can't put a name with his face.

Q. Is there a document that might refresh your recollection?

A. Hopefully, yes.

Q. What document might refresh your recollection?

A. I don't know if I had e-mail communications or text messages or how I would have communicated with him about getting together.

MR. McCAULLEY: Your Honor, may I approach the witness and --

THE COURT: You may.

MR. GALLO: Objection, Your Honor. He's not established a predicate. And the other -- the -- also the objections that I raised out of court with Your Honor.

THE COURT: You can have that objection -- that can be a standing objection.

Mr. McCaulley, I need a -- Mr. Gallo's objection.

BY MR. McCAULLEY:

Q. Do you recall, Mr. Johnson, having e-mail communications with Mr. Hair?

A. I don't remember specific e-mails, but that is the gentleman that I was referring to.

Q. Do you recall if you had any e-mail communication with him?

A. I had a lot of communication with him over the years. I don't -- I don't know specifically having a specific e-mail come to mind about that communication.

[redacted]

BY MR. McCAULLEY:

Q. Do you recall having meetings with a company called Sterile Edge?

A. Yes.

Q. Who did you speak with at Sterile Edge?

A. There was three or four gentlemen. One of them was John Harper. The gentleman from Europe, I don't recall his name, but we did have a number of meetings with that group.

Q. What did they do?

A. They were a new organization that, if my memory is correct, they were going to be providing off-site sterilization services to hospitals.

Q. Do you recall when those meetings specifically took place?

A. I -- I do not remember specifics.

Q. Is there anything that would refresh your recollection as to when those meetings took place?

A. Yes, e-mails, text messages.

Q. Do you recall having any specific e-mail communications with Sterile Edge?

A. Yes.

Q. Who would that have -- well, let me begin again.

Would the e-mail exchanges refresh your recollection as to when that meeting took place?

A. Yes. The e-mails would. I do remember specifically that they came to Chicago and met us at the lab to discuss working with them on this program.

MR. McCAULLEY: Your Honor, may I offer the document and -- to refresh his recollection?

THE COURT: He sounds like he knows, Mr. McCaulley. Do you have more questions for him about that meeting?

BY MR. McCAULLEY:

Q. Do you recall specifically when that meeting took place?

A. I do not.

Q. Do you recall specifically if you sent information to Sterile Edge?

A. I'm very confident that I did send them information.

Q. Do you recall when you sent that information?

A. I -- I don't remember specifically.

Q. Would you have sent those communications by e-mail?

A. The bulk of the communication, I would assume, would have been by e-mail.

Q. Would you -- would there be any record that would refresh your recollection of when you sent materials to Sterile Edge?

A. I would assume there would be an e-mail that would refresh

my memory of when those meetings took place.

MR. McCAULLEY: Your Honor, may I offer the e-mail?

THE COURT: You may show it to him.

MR. McCAULLEY: Would Your Honor like a copy?

THE COURT: No, thank you.

(Counsel approaches witness.)

[redacted]

BY MR. McCAULLEY:

Q. Does that document, Mr. Johnson, refresh your recollection as to when you were in communication with Sterile Edge about the Rebotix program?

MR. GALLO: Your Honor, improper recollection refresh. The witness is just going to read from the document. That's not refreshing recollection. That's introducing the document --

THE COURT: Hold on, Mr. Gallo. So he's asked you a yes-or-no question, start there.

THE WITNESS: Yes.

BY MR. McCAULLEY:

Q. When did those communications take place?

A. In October of 2019.

Q. Does that -- when did your meeting take place with Sterile Edge, if you recall?

A. Based off the time -- the time of this e-mail, I would assume it was in the fall of 2019, but I don't have a specific memory of the specific date.

Q. Do you recall --

THE COURT: Mr. McCaulley, if his recollection has been refreshed, you're to take the document back.

MR. McCAULLEY: Thank you. I was moving on.

THE COURT: Okay.

MR. McCAULLEY: I forgot to collect my document.

BY MR. McCAULLEY:

Q. Do you recall meetings with a company called Critical Insight?

A. I don't know that I have specific memories of that organization.

Q. Do you have general memories?

A. I do not recall that organization.

Q. Have you ever heard of someone called Brin Davies?

A. I'm sorry. Can you repeat that again?

Q. Have you ever met someone called Brin Davies?

A. The name sounds familiar, but I do not have a specific

memory of meeting with that person.

Q. Do you recall having any meetings with a company called H-O-A-G, Hoag?

A. If you're referring to Hoag Hospital.

Q. Are you --

A. Yes, I'm familiar with Hoag Hospital.

Q. Did you have meetings with Hoag Hospital about the robotics program?

A. I have recollections of communications with Hoag Hospital, but I do not remember specifically a robotic meeting. I don't have a memory of that specific meeting.

Q. Do you have memory of a -- meetings with an organization called SVMH?

A. I'll assume, again, that that's a hospital reference, and I'm not sure what that acronym is for, SVMH.

MR. McCAULLEY: Your Honor, may I have a moment to confer with counsel?

THE COURT: Yes.

(Conferring.)

BY MR. McCAULLEY:

Q. Mr. Johnson, as part of your participation in this case, you turned over your records; correct?

A. Yes.

Q. Again, just to reiterate, is there any doubt in your mind that you had as many meetings as you testified to last week?

A. I absolutely did.

MR. McCAULLEY: Your Honor, I'm done.

THE COURT: Thank you, Mr. McCaulley.

MR. GALLO: Thank you, Your Honor. I appreciate it.

RECROSS-EXAMINATION

BY MR. GALLO:

Q. Good morning, Mr. Johnson.

On Friday, you recall testifying about the declaration you submitted under oath to the Court in December of 2024, the one that said you had worked continuously at SIS for 14 years?

A. Yes.

Q. And you remember testifying about a deposition in 2022, where you testified under oath you had worked at SIS continuously for 14 years?

A. Yes.

Q. And you remember saying that the reason you thought you gave that sworn testimony was because the question was vague and only referred to having some association with SIS?

A. That was my recollection, yes.

Q. Yes.

And do you stand by that testimony this morning?

A. I think in that moment, as nerve-racking as it was, I wasn't necessarily focused on that specific question. But, yes, I know I made a mistake, but I do -- that's what I said.

Q. And you were sworn to tell the truth at that deposition;

right?

A. Yes.

Q. And would you look at Tab 2, page 7, lines 8 to 16, of your November '22 deposition. It's November 2022 deposition.

Tell me when you have had a chance to read lines 8 through 16.

A. I'm sorry. What page was that again?

Q. Page 7. It's right at the front of the deposition, under Tab 2. Just let me know when you're done reading it.

A. (Witness examines document.)

Q. All I'm asking is lines 8 to 16.

A. I read it.

Q. Okay.

MR. GALLO: Mr. Lee, would you please play lines 8 to 16 of page 7 of Mr. Johnson's deposition.

(Video played but not reported.)

BY MR. GALLO:

Q. Mr. Johnson, that's -- you gave -- that's the question you were asked and the answer you gave?

A. Yes.

Q. Let me direct your attention to lines 13 to 16, the next question and answer.

And you see it says "so."

"QUESTION: So that role, just to be clear, has been Executive Vice President of Sales and Clinical Programs

for the full 14-month -- 14-year period?

"ANSWER: Correct."

Do you see that?

A. Yes.

Q. That's the testimony you gave?

A. Correct.

Q. And you said specifically you had been the Executive Vice President of Sales and Clinical Programs for the full 14-year period under oath; right?

A. I always had that title, but I'm not sure that we ever put clinical programs on my business card until later.

Q. That's not what I asked you.

A. Okay.

Q. I asked you if you gave that testimony --

A. Yes, I did.

Q. And that's the testimony where you said specifically you held that title for 14 years continuously; that's the testimony you were suggesting to the jury was vague and unclear when you testified on Friday.

True?

A. Yes.

Q. You testified about Rebotix and we talked a bit about whether they were distributors and you -- I believe your testimony was you could not recall whether Rebotix had 10 distributors in the United States.

Do you remember that?

A. Yes.

Q. Okay. I'd like to refer you to Tab 62. Do you think there might be a document that would help you recall whether you knew they had distributors?

MR. McCAULLEY: Objection, Your Honor. This goes beyond the scope of redirect.

MR. GALLO: Your Honor, my recollection is that the witness was asked about Rebotix's sales force on redirect on Friday afternoon.

THE COURT: What say you, Mr. McCaulley?

MR. McCAULLEY: I don't believe so, Your Honor.

MR. GALLO: I'll move on. It's not -- if that's --

THE COURT: Thank you, Mr. Gallo.

BY MR. GALLO:

Q. You testified about your so-called -- at SIS you had a Recovery Program; do you remember that testimony you gave on Friday afternoon with Mr. McCaulley? What I'm referring to is where you would go get -- you'd pick up an EndoWrist and inform hospitals how many uses were left on the EndoWrist?

A. I don't remember discussing the term "Recovery Program," but I do remember discussing the program, correct.

Q. Right. So you'd go pick it up and you'd tell the hospital, "You have two uses left," "You have three uses left," whatever?

A. Correct.

Q. Do you remember referring to that as the recovery program at SIS or no?

A. In the field, yes.

Q. Okay. So do you understand there's no claim in this case that relates to the Recovery Program?

A. I don't know that I'm a hundred percent aware of that, but I -- not to my recollection. I don't remember discussing the Recovery Program.

Q. Okay. And you -- at SIS you charged customers for that service of picking up the device and telling them how many uses they had left?

A. Only if they bought -- only if they purchased it back.

Q. I'm sorry, "purchased it back" meaning what, sir?

A. So, we had the capability to test those arms to see if there were any remaining lives left. And what we were able to do is show hospitals that they had thrown away hundreds of thousands of dollar's worth of unused lives on their instruments.

When we would do that program, we would check it and provide the information if they requested it. But not every hospital would buy their instruments back. So they only paid if they bought the instruments back to recover those dollars that were thrown away.

Q. Okay. So if they bought it back, you charged them and

they paid you?
A. Correct.
Q. Do you know that a customer with an EndoWrist can simply call Intuitive customer service and be told how many lives are on the instrument without charge?
A. I didn't know that specifically, but I would assume that that is something they could do. I --
Q. Did you tell customers that when they --
A. Did I tell customers what?
Q. That they could do it for free without paying you? They could get the same information for free?
A. I never -- I don't think I ever told anybody that because I don't think I was aware of that.

The only way I knew that customers could check their arms was to plug them in the robot. I didn't know that -- in all honesty, I didn't know that they could call, and you guys would randomly be able to randomly provide that information.
Q. Did you know if they plugged them in the robot, they could get the same information for free by just plugging it into the robot and using one of the portals that EndoWrist -- that da Vinci customers regularly used?
A. I knew that, correct.
Q. And did you --
A. I didn't know how many people took advantage of it.
Q. And did you know that they wouldn't be charged for that by

Intuitive?

A. I don't think I knew that, but I guess it's safe to assume.

Q. Did you tell customers that when you charged them, that they had this other alternative that was free of charge?

A. Well, we didn't charge them if they didn't get their instruments back.

Q. When you did give them the instruments back, did you tell them they can simply get it for free from Intuitive, the same information?

A. I don't think I told anybody that because, like I said, I didn't know that that was a thing, that that was a service.

Q. Okay.

A. If it wasn't plugged in the robot, I didn't know you guys had the capability to tell them how many lives are remaining on the instrument.

Q. Okay. You also talked about a pre-owned program of some kind where you would collect an EndoWrist from a customer, right? And did I understand you to say that then you would then sell it to a different hospital? Is that what the program was?

A. Correct.

Q. Okay. And do you know there's no claim this case related to the pre-owned program either?

A. I -- like the other one, I did not know either way.

Q. Okay. And when you picked up an EndoWrist from Hospital A and you sold it to Hospital B, obviously SIS would get some money; right?

A. Correct.

Q. Did you -- who -- did you give any of that money to Hospital A?

A. No.

Q. Okay. You kept it for yourself?

A. Correct.

Q. Okay.

Just a couple more subjects, three, to be precise.

Flexible EndoWrists, you were asked some questions about flexible EndoWrists in your examination on Friday; right?

A. Flexible endoscopes?

Q. Endoscopes. I'm sorry. Apologies.

A. Yes.

Q. Flexible endoscopes, right.

So have you -- has SIS ever repaired -- do you know there's a thing called a single-use flexible endoscope, supposed to only use it one time?

A. There's a number of them, yes.

Q. Has SIS ever repaired a single-use flexible endoscope so that it would be used more times than the manufacturer recommended?

A. I don't have specific knowledge that SIS has done that.

Q. You're not aware of SIS ever having done that; right?
A. Not that I can remember, no.
Q. Okay. And I don't want to be too graphic here; but just so it's clear, an endoscope is used to enter an orifice of the human body, for example, the mouth; correct?
A. Correct.
Q. And then it goes down the throat?
A. Mm-hmm.
Q. Or -- and there's an orifice that goes into the colon, for example?
A. Mm-hmm.
Q. And it is -- matter in the regular lives, goes down people's throats, right; into your mouth, down your throat?
A. Correct.
Q. And same with the colon, matter passes through the colon; correct?
A. The scope goes into the colon?
Q. Where does it go?
A. Yes. So you have a gastroscope that goes down into your esophagus, and you have a colonoscope that goes up into your colon.
Q. Right. And the endoscope is basically a tube, sometimes with a light on it, to allow the physician to see what's going on in those orifices; correct?
A. Yes.

Q. And it can be used, and typically often is used, as just a stand-alone instrument; right?

A. I don't know what you mean by that.

Q. I mean, it's not part of a complex integrated medical system like that; right?

A. It doesn't have a robot, but it does have a light source and a processor.

Q. A light source, right?

A. And a processor, correct.

Q. Okay. Do you know how much force is applied to an endoscope when it is used, for example, to go down someone's throat?

A. On an EGD, not a lot; on a colonoscopy, much more.

Q. Okay. But can you give me kind of a precise measurement?

A. No.

Q. And can you give me any kind of measurement how precise the movements of an endoscope are inside when it's being used? I'm asking for some kind of quantification, some kind of measurement.

A. Yeah. I know angulation. I wouldn't know much more than that.

Q. Okay. And let's talk about the EndoWrist. You understand that it's used as part of the da Vinci system; right?

A. Correct.

Q. And it's integrated into that entire system; right?

A. Correct.

Q. And it doesn't go into natural orifices of the body?

A. No.

Q. It goes into an incision. That is not typically made to go into the abdomen or other parts of the human body; right?

A. Correct.

Q. And once it's inside the human body, do you understand it makes precise microscopic movements to conduct surgery?

A. Yes.

Q. And you don't know how to measure those movements, do you?

A. I'm not an engineer, right.

Q. So when it cuts through an artery, for example, do you know the precision with which it moves?

A. No.

Q. Or when it cuts through -- for example, when it's doing surgery involving the uterus, do you know the precision with which the device moves?

A. No.

Q. And you -- and I believe I'm correct that you don't have SIS -- any knowledge of SIS ever replacing the cables that control those precise movements?

A. No, we did not replace cables.

Q. Okay. I want to refer you back to two questions for context of what you testified to, and then I have one follow-up question.

Recall you testified on Friday that you knew that, sometime before Rebotix worked with SIS, it had applied for FDA clearance for its work on the EndoWrist?

A. On Si --

MR. McCAULLEY: Your Honor, goes beyond the scope of redirect.

MR. GALLO: I'll ask the one -- I was just trying to put it in context. I'll go right to the one question that Mr. McCaulley objected to and we agreed we would revisit.

BY MR. GALLO:

Q. The one question was, you learned -- so you -- SIS and Rebotix worked together in 2019 and early '20, right, on this program?

A. Correct.

Q. You learned, some period of years after 2019 and early '20, that Rebotix had qualified as an authorized third party under Intuitive's policy; right?

A. I did agree to that, but I still, over the weekend, thought in my head, sir -- I don't even necessarily know if I know necessarily what that means, qualifies. I don't -- I hadn't heard that before.

Q. Okay. Let me be clear about this. Some period of years after Rebotix stopped working with SIS, you understood that Rebotix was -- had met the criteria to qualify under the Intuitive policy, didn't you?

MR. McCAULLEY: Your Honor, I object to this. My understanding was he was precluded from testifying about that.

THE COURT: No. He's allowed this.

BY MR. GALLO:

Q. You can answer me yes or no, sir. If you don't know, you don't know. That's fine. I just want to know --

A. I was familiar -- I -- from what I understand it to be, I'll say yes.

Q. Okay. Last line of just the three or four questions.

You know that SIS never approached Intuitive to seek approval as an authorized third-party seller of EndoWrists; right?

A. Not that I know of.

Q. It never took steps to qualify as a third party authorized by Intuitive; right?

MR. McCAULLEY: Objection. Beyond the scope of redirect.

MR. GALLO: I'll move on. I think I asked it already.

[redacted]

[redacted]

MR. GALLO: Okay. Thank you. Thank you, Your Honor. Thank you, Mr. Johnson.

THE COURT: Thank you, Counsel.

Mr. McCaulley, do you have anything else for Mr. Johnson?

MR. McCAULLEY: No, Your Honor.

THE COURT: All right.

Mr. Johnson, you are thanked and excused.

(Witness excused.)

THE WITNESS: Just leave this here?

THE COURT: Yes.

Mr. McCaulley, call your next witness. I'm not sure who to ask on this side.

MR. VAN HOVEN: The two depositions that Your Honor ruled on this morning are ready, and the parties have approved them.

THE COURT: You're welcome to use them.

MR. BRACHMAN: Your Honor, just briefly. I don't believe we've seen the recut clip reports.

THE COURT: All right.

Counsel, let me suggest this. It sounds like you're ready for the depositions and you may need five minutes to sort of sort that out. Let me -- it's early yet but let me give you-all a five-minute break just to stretch and let them get those things ready to go so that when you come back, we're ready to play them for you.

So let's all rise for the jury.

(The jury leaves the courtroom.)

[redacted]

(The jury enters the courtroom.)

(Proceedings were heard in the presence of the jury.)

THE COURT: You may be seated.

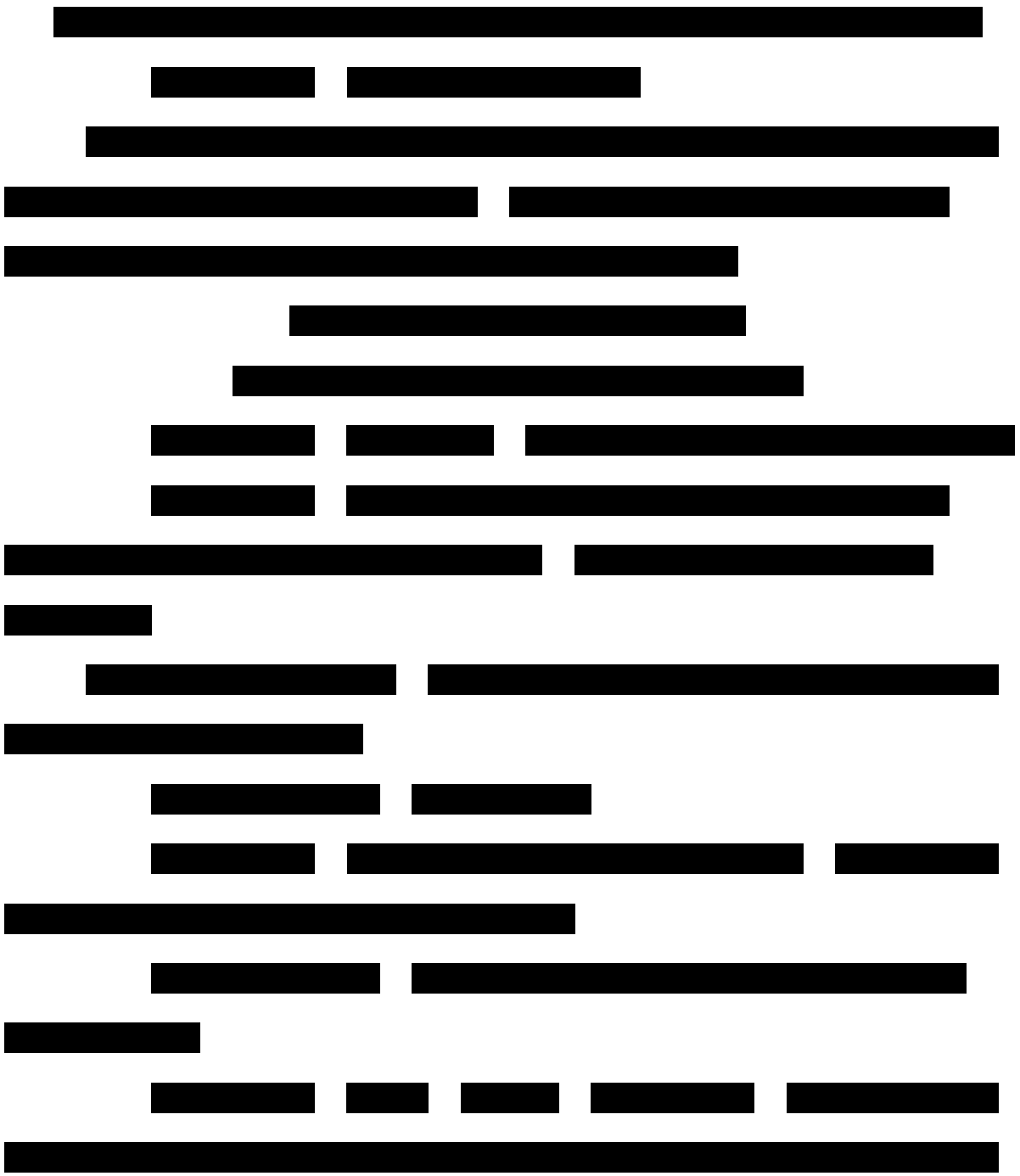
MR. VAN HOVEN: You will now hear deposition testimony from Robert DeSantis. Mr. DeSantis was employed by Intuitive Surgical and held the title of Executive Vice President and Chief Product Officer at the time of his deposition which was taken on May 27, 2021.

(Video played but not reported.)

THE COURT: Mr. Van Hoven, pause the video for just one moment. I think we need a five-minute recess.

All rise for the jury. Please.

(The jury leaves the courtroom.)



[redacted]

(The jury enters the courtroom.)

(Proceedings were heard in the presence of the jury.)

THE COURT: You may be seated.

Thank you-all for that unexpected brief break. We're going to -- plaintiffs' counsel is going to bring the deposition a minute or two back, just to give you-all context for where you were before we recessed.

(Video played but **not** reported.)

MR. VAN HOVEN: You will now hear deposition testimony from Anthony McGrogan. Mr. McGrogan was employed by Intuitive Surgical and held the title of Vice President of Design Engineering, Single Port Platforms at the time **of** his deposition taken June 7, 2021.

(Video played but not reported.)

MR. VAN HOVEN: SIS calls Dr. Kim Parnell.

THE COURT: All right. While they get him, let's go ahead and stretch.

(T. Kim Parnell steps forward to be sworn.)

THE CLERK: Please raise your right hand.

TOBY KIM PARNELL,

called as a witness for the Plaintiffs, having been duly sworn, testified as follows:

THE WITNESS: I do.

THE CLERK: Please be seated and spell and state your full name for the record.

THE WITNESS: My full name is Toby Kim Parnell. T-O-B-Y; middle name Kim, K-I-M; last name Parnell, P-A-R-N-E-L-L.

DIRECT EXAMINATION

BY MR. VAN HOVEN:

Q. Good morning, Dr. Parnell.

A. Good morning.

Q. Could you briefly introduce yourself to the jury?

A. Yes. So as you heard, Toby Kim Parnell. I'm a mechanical engineer. I have an undergraduate degree from Georgia Tech and then Stanford; I went to Stanford for master's and Ph.D. in mechanical engineering. I'm a licensed professional mechanical engineer.

Q. And when did you get your Ph.D. from Stanford?

A. 1984.

Q. And could you briefly summarize your work history since you got your Ph.D.?

A. Yes.

I spent some 13 years at Exponent, which is a large engineering scientific consulting firm. And then in 2000, I left and started doing more medical device-type work and started working as a consultant and worked for a number of small companies, doing a variety of activities associated with medical devices.

Q. And what is Exponent?

A. Exponent is a large engineering scientific consulting firm. They're headquartered in Menlo Park.

Q. What sort of work did you do at Exponent?

A. Exponent, being a consulting firm, you really do a number of different types of work, depending on the project. The company was originally known as Failure Analysis Associates. A lot of the tasks -- a lot of the projects involved accident and failure analysis types of activities, but also -- also other --

other things in terms of looking at reliability and analysis of devices and how they operate and how they perform.

Q. Have you ever had any positions in academia?

A. Yes, I have. I taught one quarter at Stanford in graduate -- graduate courses -- course in mechanical engineering. Also I spent two years at Santa Clara University, on a full-time basis, teaching undergraduate mechanical engineering courses. And that really covered a variety of things involving design, analysis, materials, and also some more specialized courses, like finite element analysis.

Q. And what is your current position or employer?

A. I'm self-employed. I'm a -- work through my company, Parnell Engineering and Consulting. So I'm a sole proprietor and I do work through -- on that basis, then.

Q. What sort of work do you do at Parnell Engineering and Consulting?

A. Work like this is one example. Some of my projects are litigation-related types of projects, may involve patents, may involve other -- other types of issues such as that.

Over the years, some of that has also been medical device-related, helping companies with design-related issues and development-related issues for medical devices.

Q. And I guess -- so the consulting firm does a mix of litigation and engineer consulting work?

A. Yes, that's correct; that's correct.

Q. And you've been retained by Surgical Instrument Service Company in this case?

A. Yes, I have been.

Q. What is your compensation in this matter?

A. $650 per hour.

Q. And does that compensation in any way influence the opinions that you're giving today and that you've given in this matter?

A. No, it does not. My retention is to give honest and unbiased opinions. I don't have a stake in the case, in the outcome of the case or anything like that. So I'm just here to provide my opinions.

Q. And have you prepared any reports in this case?

A. Yes, I have.

Q. And in preparing those reports, did you review any materials or documentation?

A. Yes, I did.

Q. What sort of materials and documentation did you -- did you review in preparing your reports?

A. Well, in a litigation matter like this, there's always a great deal of documents and -- that are produced. I reviewed all the documents, reports, deposition transcripts and things like that that I had access to. It also included more detailed procedures associated with the service procedure.

Q. And did you review documents from Intuitive?

A. Yes, some -- some were Intuitive documents.
Q. Do you have any idea about how many you looked at or...
A. No. I'm afraid -- it's -- it's a large number. I don't -- I don't know. I don't have a count, though, I'm afraid.
Q. Did you review any Rebotix documents in preparing your opinions in this matter?
A. Yes, I did.
Q. And how would you characterize the amount of documents that you reviewed from Rebotix?
A. The documents were -- were significant, certainly for -- from Rebotix, there were detailed documents associated with the service procedures that they had developed. There were also other types of transcripts and things of that sort that were associated, reports produced, so it covered a range.
Q. I'd like to ask you about a couple engineering subjects.
One is failure analysis. Do you have an understanding what failure analysis is?
A. Yes.
Q. Could you describe that to the jury?
A. Yes. Failure analysis can come up in a number of different circumstances. One you can think of is maybe when a product has some type of a -- of a break or a failure and no longer performs its function.
And so you want to be able to understand the cause of that

problem, whether it -- whether it be materials associated or some sort of design issue or overstress or overload. It's really just getting a handle on the cause of the problem.

Q. And another term I'd like you to describe, if you're familiar with it, is reverse-engineering?

A. Yes.

Q. What is reverse-engineering?

A. Reverse-engineering most often comes into play when you have a -- a product or a component and you're trying to understand more about how that product performs, maybe even to try to develop specifications, performance specifications for that product. So you're -- you're evaluating how it operates and maybe making measurements, things to decide, okay, the -- the degree of movement, the geometric specifications, things like that.

Q. Is reverse-engineering fairly common in the engineering field?

A. Yes. It often comes about. You know, you may be handed or exposed to a product and not really have access to the manufacturer's specifications, and so you're trying to develop some insight on that product through the reverse-engineering process.

Q. So you understand this matter relates to something called EndoWrists; right?

A. Yes.

Q. And have you had a chance to review documentation or other information about the function and operation of EndoWrists?

A. Yes, I have.

Q. Could you generally describe that to the jury?

A. Documentation includes quite a variety of different things. There's a lot of documentation that was produced from Intuitive Surgical, covering various aspects through their own development and testing cycle, for example.

A lot of information related to evaluation of their instruments, information associated with instruments that were returned and analyzed in some cases, you know, where Intuitive did failure analysis on some of these instruments and -- to understand the cause of a particular issue.

So it -- it covered quite a number of different things. There's a lot of documentation produced in a case like this.

Q. Did any documentation from Rebotix inform your understanding of how EndoWrists operate?

A. Yes. It did.

Q. Did you have an opportunity to see EndoWrists in person, live?

A. Yes, I have, on several different occasions.

Q. What, to your understanding, of when the EndoWrist design was initially developed?

A. Time frame, I think roughly in the early 2000s, maybe even a little bit into the late 1990s. But early 2000s is when it

was being developed as a -- and released as a commercial product.

Q. And do you understand that there are two generations of EndoWrists that are at issue in this matter?

A. Yes.

Q. And could you explain your understanding to the jury?

A. Well, the earlier generation of -- of EndoWrists had the designation of basically S and S subscript i. So S/Si is a designation you often see. And then next generation of devices had designation of X and X subscript i. So that X/Xi designation you see on later generations of devices.

Q. And I'd like to talk a little bit about the structure and function of the EndoWrists, if that makes sense.

A. Sure.

Q. And I guess, I'd like -- do you understand that the EndoWrists have something that's generally called a proximal end and a distal end?

A. Yes.

Q. Could you explain what that means in the context of an EndoWrist?

A. Yes. So in -- in an EndoWrist, the proximal end is the end of the device that actually mounts to the da Vinci robot, so that's the mounting end.

And the distal end, typically, medical devices, it means the other part. It may be the part that interacts with a

patient, then. So in the EndoWrist, the distal end is the end that has the tool or the operating component of the wrist that's being driven during a surgical procedure. So that's the part that would be in -- in a patient during a -- a surgery of this type, then. That's the part that would be in the patient to do a certain operation, then.

Q. And is there some sort of drive system connecting between that proximal end and that distal end?

A. Yes. The input drive comes back at the proximal end. That's, again, where we talked about the connection to the robot.

And there are basically four drive components that mount there. And -- and that -- that drive input is transmitted to the distal end of the device.

Q. And focusing back at the proximal end that couples to the robot, how is force delivered to turn those disks to make them operate?

A. It's through motors that are controlled. And they receive input -- they're controlled by the surgeon still, you know. Surgeon's got a console and the surgeon is providing the commands or the -- the input to make the -- move those components, then. And there's basically 4 degrees of freedom back there that he has to operate.

Q. And where is that -- where are those four motors located?

A. The motors themselves are on the arms of the

Intuitive Surgical da Vinci robot.

Q. Are there any motors or other drive components inside the EndoWrist itself?

A. Not -- not at the distal end, if that's what you're asking.

Q. I guess I'm asking are there any motors within the EndoWrist at all.

A. No, no, there's not.

Q. Are there any active electronics within the EndoWrist that control its operation?

A. In terms of electronics, the only thing back there is associated with usage counter. That's the only real electronics that's there. Maybe I should qualify that a little bit.

There is also connection for some instruments are, termed broadly, like, electrosurgical instruments. They'll have an electrical input to -- let's say, to cauterize tissue, or to do some operation of that sort.

Q. But those electrosurgical input -- connections, do those affect the drive system of the EndoWrist?

A. No.

Q. Going back to the drive system, could you provide -- discuss the -- what physically connects the motion at the robot arm to movement at the distal end?

A. Yes. It's -- it's a cable-type system, and it's really a

system that has a short piece of tungsten cable, braided tungsten cable at -- both back at the proximal end, connecting to the robot, and then also at the distal end.

In between that, the -- those short pieces of cable, flexible cable are clipped to stainless steel rods, basically fairly rigid rods that transmit the motion, then, down the shaft of the EndoWrist to the cable at the other end.

Q. And so within that, I guess -- what do you mean when you're talking about the rods within the shaft of the EndoWrist? What are you talking about there?

A. Just talking about how the cable input connects to a rod. That rod is down the shaft of the EndoWrist. And then there is another short piece of flexible cable at the other end. So think of it as each end has a short piece of cable, and there's a rod in between those two short pieces of cable, then.

Q. What's your understanding of the material of the rod that passes down the long shaft of the EndoWrist?

A. Yeah, the rods are stainless steel.

Q. What's your understanding of -- I guess the strength of that material?

A. It's significant and it's a solid-type material. It's not undergoing any bending or flexure. It's really just a kind of a -- a longitudinal push/pull-type loading on it.

Q. And in connection with the -- the cables that we were talking about, how do those connect to the rods?

A. They are crimped to the rods so that there's a strong connection between the cable and the rod just through a crimp process.

Q. And are there any pulleys or anything involved in the drive motion with the cables?

A. Yes, definitely. The cables, the flexible cables, are routed through pulleys. There's some pulleys at each end really, back at the proximal end to carry from that input motor drive to the cable and to the rod. And then down at the distal end, where you have the working end of the instrument, there are pulleys that the cables route around at that end also. That's how you get the degrees of freedom, the amount of movement associated with the working end, the distal end of the EndoWrist.

Q. And you talked earlier about two generations of -- of EndoWrists. Do you have -- have you a general understanding of the differences between those generations as to their general function and structure?

A. Yes. General understanding, yes.

Q. Could you explain that to the jury, please?

A. One aspect is maybe the most visible, just if you held up an EndoWrist from the S/Si, earlier generation, and the X/Xi, is how it mounts to the arm of the da Vinci robot.

The S/Si is basically kind of a -- an in-line type of mount, with the shaft to transmit down to the end.

The X/Xi mounted -- went through, basically, a 90-degree angle to mount to the robot and then to transmit down the shaft.

The working end of the instruments, largely the same. I mean, there were some design changes that were made during this time, but largely the same, though, when you look at them.

MR. VAN HOVEN: I understand no objection to TX475?

MS. PARKER: No objection.

MR. VAN HOVEN: Could we, Your Honor, move 475 into evidence and publish to the jury?

THE COURT: You may. It's admitted and you may publish it.

(Trial Exhibit 475 received in evidence.)

BY MR. VAN HOVEN:

Q. Dr. Parnell, can you see that document, or would you like it zoomed in on maybe the top couple of paragraphs initially?

A. Yes, that helps. Do you want me to read the top two paragraphs?

Q. Just are you familiar with this document?

A. Yes, I am.

Q. Do you have an understanding of what this document was intended for?

A. Yes. It's talking about some of the life testing being performed on the Xi range of instruments and similarity with the Si's.

Q. And if we can move down to the bottom paragraph of that page.

A. Yes. So this last paragraph on the page is talking about similarities between the S and the Si. The instruments are similar in many regards, the materials used in the distal portion of the S/Si 8-millimeter are identical to those used in the equivalent versions of the Xi 8-millimeter instruments.

MR. VAN HOVEN: Could we move to the top of page two?

Q. Take a look at that and let me know when you're ready to talk about it.

A. (Witness examines document.)

Yes.

Q. This is using some of those terms we had, like proximal; but it also gets into input, output, gear ratios and band radii. Do you mind explaining to us, in a little more layman's terms, what this is talking about?

A. So this is talking about -- well, one that's mentioned is that back at the back end, where you attach to the robot, that there's that change in the angle of the mount. But it's talking about the things that are similar and that are basically designed to be identical.

So cable paths through the wrists of the instrument, so this is how the cable runs through the pulleys and down at the distal end of the shaft and to the cable attachment points on the various joint output pulleys for the yaw, grip, and pitch.

These are associated with the 4 degrees of freedom that are down at the distal end, are designed to be identical.

MR. VAN HOVEN: Could we move to the next two paragraphs and heading?

Q. And again, sort of same question, could you take a look at that and kind of try to put that into a little more layman's terms for us?

A. (Witness examines document.)

Okay.

Q. Please, go ahead.

A. So this is talking about some more specifics associated with cable -- cable tension, for example, and how that's generated in the instrument by applying torque to those input drive -- drive pulleys where the cable is clamped. So this is back again up at the proximal end and where it's connected to the robot. And it's talking about things that are intended to be similar, to have the same kind of sizes, the same diameter of the clamping pulley so that the system torque limits -- the torque being the kind of rotary force, if you will. You can think of as inch pounds. It's a force and a length, is what you do to get a torque. The applied system torque limits can be directly compared.

Range of motion between S/Si and X/Xi is designed to be identical.

So these -- these two paragraphs are -- are basically

trying to indicate the things that are basically the same between the two generations of devices.

MR. VAN HOVEN: And could we go to the bottom of page 5, last paragraph.

[redacted]

BY MR. VAN HOVEN:

Q. Would you mind describing what this paragraph is explaining to the jury?

A. Yes. It's basically a justification for why testing that is performed on the Xi, the newer generation of instruments, is adequate or sufficient to cover the S/Si. And so they were basically going to provide some justification for how to apply, let's say, conclusions. This talks specifically about reprocessing appendices, so these are associated with cleaning and sterilization steps, why it applies to the Si family of instruments also.

Q. Based on your -- your own review of documents and other information about Si and Xi instruments, do you agree with Intuitive's statements about the similarities between those instruments that we've discussed?

A. I think so. You know, there's definitely significant similarities there. There's some documents that showed differences in, shall we say, numbers of devices that came back through their RMA process. I may talk about that later.

But, yeah, I certainly agree that there's significant similarities in commonality between the two families of devices.

Q. And do you have an understanding of when Si was introduced versus Xi?

A. I believe the S/Si was in, roughly, 2010 time frame, maybe a little before or after that.

And I think the X/Xi around -- just going from memory, I think around the 2015 or so time frame, a little after that.

MR. VAN HOVEN: We can pull that down.

BY MR. VAN HOVEN:

Q. One of the things that you've been asked to look at is failure of EndoWrists; is that right, Dr. Parnell?

A. Yes.

Q. Are you familiar with failure mode?

THE COURT: Brief recess?

Can I ask you whether -- Mr. Van Hoven, how much longer do you --

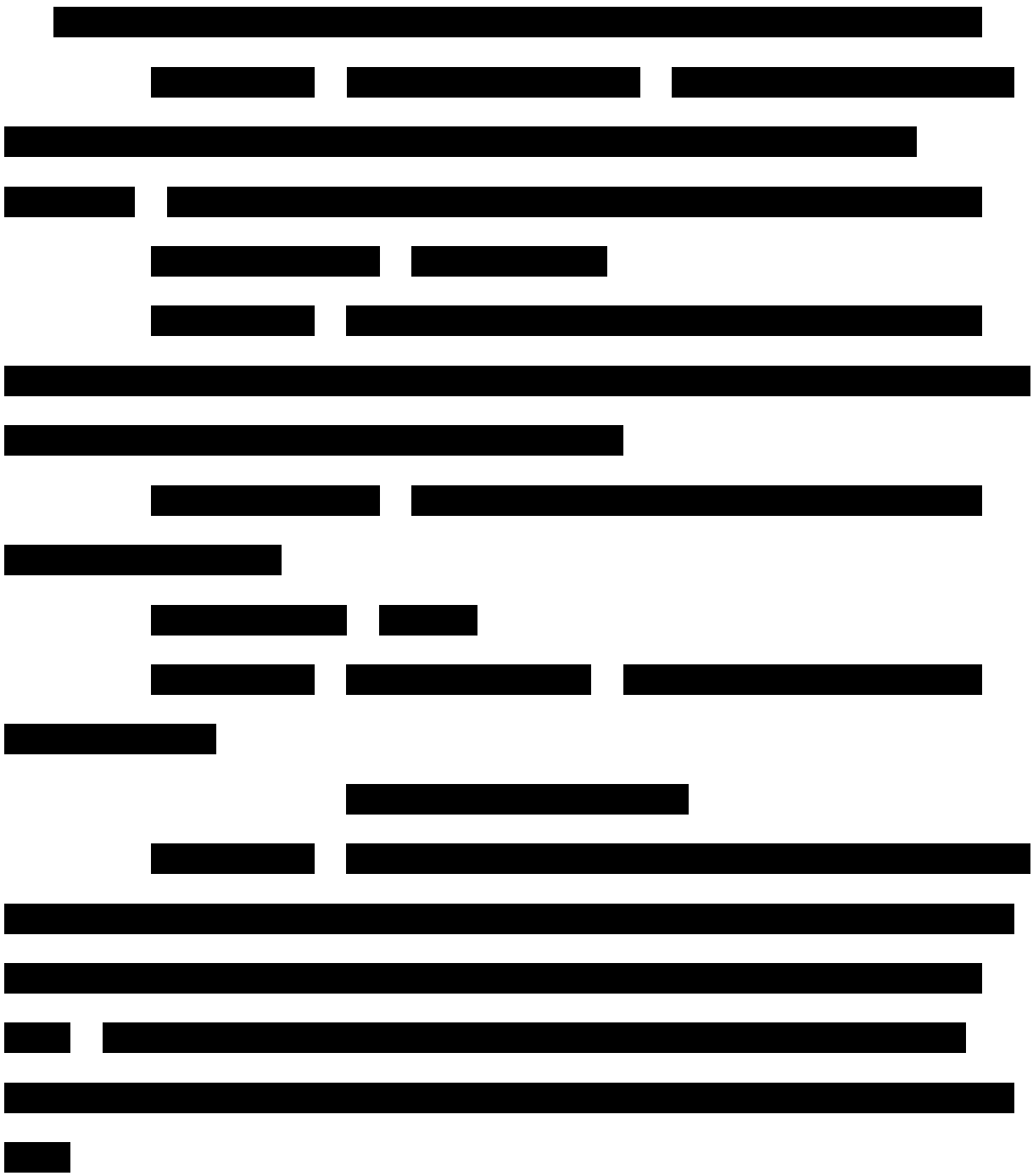
MR. VAN HOVEN: I was just starting a whole other line here. But, yeah.

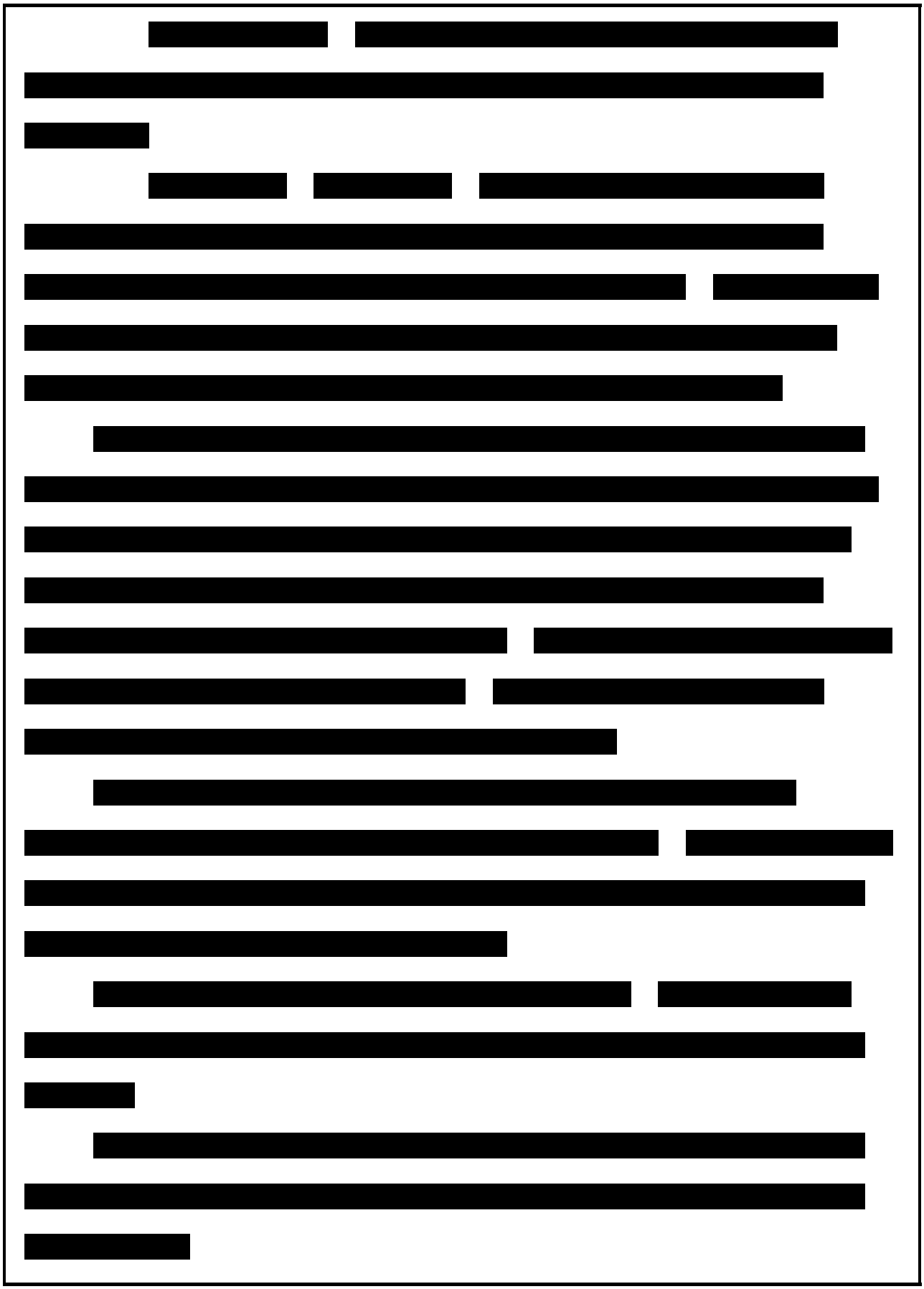
THE COURT: We're going to give you a brief recess

now. I thought we would break around 11:45 for lunch. Maybe we can take a brief break now and break closer to noon for lunch. All right. Let's do that.

All rise for the jury, please.

(The jury leaves the courtroom.)





[redacted]

(The jury enters the courtroom.)

(Proceedings were heard in the presence of the jury.)

THE COURT: You may be seated.

BY MR. VAN HOVEN:

Q. Dr. Parnell, have you heard the term "failure modes"?

A. Yes.

Q. Can you explain to the jury what failure modes means in the context of mechanical engineering?

A. In general, it means to more specifically understand what's causing a specific failure or issue. So it's kind of getting down more to the details of what the underlying cause is. You know, is there -- is there -- are the loads too high? Was it, you know, an upset-type condition, meaning something that is unusual, is outside of the usually operating realm or a material issue? It's really just getting more specifically to the type of issue.

Q. And did you perform any analysis of failure modes in the context of EndoWrists?

A. Well, you know, through both documents and -- and EndoWrists that I had access to through this project, I saw a number of different types of failures or issues at different times. You know, certain ones would have certain specific types of issues and it might be different. But there's kind of a collection of things that are most frequently associated.

Q. Let's talk first about the types of failures that you understood to occur with EndoWrists. Could you describe some of those to us?

A. Sure.

So some of them are things like -- just where there's a type of a function that's not working any longer. For example, some of the EndoWrists have -- are basically scissors type of devices that are intended to cut tissue, for example, and they may not be cutting any longer. They've gotten either dulled or

they've gotten damaged through some operation, and they're just not performing their function any longer.

There's other ones, of course, devices that are used to grasp or hold tissue and maneuver it that can be no longer performing their operation.

And then, you know, other types of issues, also, that come up.

Q. And within the EndoWrists, what are some of the components that may fail to have those results?

A. Well, okay. For the ones -- like I mentioned, scissors or grasping, that can mean damage or alignment that's needed.

There can be issues with the cables elongating or some -- some issues with cables so that the device is not -- is not carefully transmitting the input motion to the distal end. They don't respond together in kind of a one-to-one fashion.

There could be others that involve more significant damage to a cable. There could be a cable that's frayed or actually gotten broken or damaged from another instrument. So there's a number of different types of things that come up.

Q. And stepping now to the sort of things that cause failures in EndoWrists, did you investigate that issue?

A. Yes, largely through looking at -- looking at documents, looking at investigations that were done as part of EndoWrists that were returned. There's some of these through what they call an RMA process, Return Material Authorization process.

And in some cases, those devices are investigated more carefully to see what had happened or what issue is associated with that particular return.

Q. And what's your understanding as to how -- the way that an EndoWrist is used in surgery relates to its potential failure or failure modes?

A. Well, certainly things specific to the given use. These things can have a factor. How long it's used in a particular operation could be a factor.

How many movements that it undergoes, how many movements of each degree of freedom is involved.

The loads associated with it, you know, is it -- is it something that requires a significant load or significant force to carry out; you know, all of these are the types of things that can contribute to a given issue.

Q. Is it fair to characterize that as the kind of the severity of the use in an actual surgery?

A. Yes, yeah, it could be associated with that.

Q. And did you do any investigation into, I guess, variance between that severity in different surgical procedures?

A. I'm not sure -- I mean, to the extent that there are certainly differences. Some surgeries can require significant amounts of time, significantly more amounts of time of one thing versus another.

The number of movements or operations that take place

and -- by a person, I mean, actuations that take place in a given surgery can be different and can be significantly different in some cases.

Q. And when you're talking about the severity of usage within a surgery, is the -- how does the torque that is applied by the robot arm to the EndoWrist disks -- how does that translate to severity of usage within a surgery?

A. It really means that the more torque that's required to carry out a given step, it -- it's a -- it's a factor. I mean, the more -- this is the loading kind of component that we talked about in terms of some type of a failure, analysis of a failure, so the torque is associated with load: how high is the load that's being applied, and how much is necessary to perform a specific function or step?

Q. So if you had available to you the torque at each of the four motors that correspond to the input disks of the EndoWrist, what would that tell you about the severity of a use during surgery?

A. It would give you kind of a log, kind of a black box type of analysis of the spectrum of steps that it went through, and how high the loads were associated with each individual step. So it would be really something of a detailed recording of the full-load spectrum that was applied in a given procedure.

Q. And is that something you would then look at if you're trying to assess the severity of a procedure?

A. Yeah. That would be something you might look at to better understand what took place, what was required in a given procedure. And maybe even to identify if there's something that's unusual in that procedure, something that led to high loads being applied.

Q. Do you have an understanding as to whether Intuitive has all that data available to it?

A. I did see Intuitive testimony from Grant Duque, for one, that that type of information is sometimes used in analysis of a specific failure, that they go back in and look in more detail associated with that. Not done each time, but it indicated that there is quite detailed information that can be obtained and can be examined to look at and better understand a particular failure.

Q. Do you have an understanding if that information is used in any way with the use counter of the EndoWrist instruments?

A. No. It doesn't come in to the use counter at all. The use counter is strictly that. It's just a use, being mounted to the robot and going through some kind of motion.

You know, an analogy might be kind of like starting your car. A use is just that, it's just a use. Nothing about details of the procedure or how long it -- analogy to the car, how far you've driven, how long the trip is, no information beyond just that we've got a use.

Q. I'd like to move to your experience with Rebotix a little

bit.

MR. VAN HOVEN: Counsel, no objections to demonstratives?

MS. PARKER: As long as they're the ones I've got, no objections.

MR. VAN HOVEN: Could we just bring up for now just the first slide?

BY MR. VAN HOVEN:

Q. Dr. Parnell, I understand that you've looked at Rebotix documentation. Did you do anything else to inform your opinions on the Rebotix process?

A. Yes. I also had an opportunity to make a site visit to Rebotix, and so to be able to see steps of their procedures that they had developed, to see that firsthand, talk to Rebotix staff, get questions answered and things like that. So, you know, it's really kind of that -- that firsthand look at things that were involved in their process, in their service process.

Q. Did you review documents while you were there?

A. Yes. I did.

Q. And you also reviewed more documents as part of preparing your report?

A. Yes. Yeah, definitely, a lot of things in more detail after -- after the visit and, you know, that led to some additional follow-ups with staff there.

Q. I guess, are you able to kind of categorize the different types of documents that you reviewed both at Rebotix and outside of it regarding their process?

A. I guess I would characterize them really as detailed process or procedure types of documents, things that outlined the steps in their process and what is done.

Also, information that they developed through reverse-engineering, certain specifications for a given type of Intuitive EndoWrist and more details associated with each one.

Q. Where is the Rebotix facility?

A. It's in Florida. I believe St. Petersburg, I believe.

Q. And about how long were you present at the facility?

A. I had a one-day site visit.

Q. And did you have anybody -- a guide while you were there?

A. Yes. My primary contact during the site visit was Mr. Fiegel of Rebotix. He's the Director of Operations for Rebotix.

Q. And what was your understanding of what Greg Fiegel's role was at Rebotix?

A. Well, it was Director of Operations. He has kind of overall responsibility for process and development of procedures and how they're carried out by staff during a service process.

[redacted]

[redacted]

Q. I guess what kind of building was it when you visited?

A. It's basically an office/laboratory type of environment. So there are offices; but there's also lab spaces, benches, equipment, things like that that are available there. So it -- kind of a typical sort of environment for a company that's going to be involved with medical devices, medical types of procedures.

MR. VAN HOVEN: Bobby, if we could go to Slide 23.

BY MR. VAN HOVEN:

Q. Before we jump into discussion of the Rebotix processes, I'd like to take a look at this slide quickly.

What is this showing?

A. It's showing several things. It's showing several different S/Si generation EndoWrists. The covers are off. So back here at the right side in this photo, the cover is off so that you see more of the -- the spools or pulleys where the cables are attached. That's back here at the right side, which is the proximal end.

Then -- yes. So the -- highlighted back here at this end, you're seeing that in a little more detail because there's a cover that's removed from it to be able to show this.

Q. And, I guess, this is a good time to understand the terms "proximal" and "distal." Could you point out where the distal end is to us on one of these tools?

A. So in this photo, the distal end, where the tool is, is the left end, the left side in this photo. And so you'll see some of the instruments, like this, you can see that distal end of the instrument here.

Q. Going back to the slide, there's something above the four instruments there. What is that?

A. That is a board that Rebotix developed, a little auxiliary board, and you'll see it referred to sometimes as the Interceptor chip. It's, basically, one that contains a little chip or semiconductor device that is associated with being able to reset -- do a reset of the usage counter. So this is what facilitates that part of the process.

Q. And there's also a long -- and elongated items below the EndoWrists. Could you explain what those are?

A. Yes. So on that EndoWrist that's at the bottom, at the -- right above this, this is the -- the distal tool and the rods and cables associated being removed. This is not a typical step. This is just to illustrate what -- what they're like.

So back at the right-hand end you see the cables that

would be in that proximal end of the device that would wrap around the input pulleys there. And they're still attached. A similar length of flexible cable down at the left-hand side, which is the distal end associated with carrying out the operation.

So this is sometimes referred to as, like, wristed movement, you know, that it allows for something that can pitch, that can move like so; it can rotate, a resolution. And then there's also a degree of freedom that's often referred to as a yaw direction, so there are two of those. That's kind of where you do the operation, then. Sometimes it's called yaw and grip, then, but that's where you carry out operations like that.

Q. So each of those assemblies is related to one of those motions; is that right?

A. Yes. That -- that's right. Each one comes in with an input from the da Vinci robot back at the proximal end of the device, where it mounts to the robot. And there's an input, basically, that involves a rotation of that device back at that end, and that leads to the transfer of the motion.

MR. VAN HOVEN: Could we zoom in on the right side, where there's a connection? Bottom right -- no, I'm sorry, that same -- the assembly there, yup.

BY MR. VAN HOVEN:

Q. And could you explain what this is showing here?

A. Yes. I mean, what you're seeing is the length of the flexible cable that is back at the -- at the proximal end of the device. This is how much cable there is there to go through a pulley and to go around the mounting or input drive connections back there.

And then you'll see -- you'll see where it's attached or crimped to the stainless steel rods. That's where you start to see the solid portion there that's more to the left side. I know it's not super clear, but you kind of get a sense of the length of the flexible or cable portion versus the length of the rods.

Q. And in your investigation of this matter, when you hear about cable breaks or cable tension, what component do you understand that to be referring to?

A. That's really referring to the flexible tungsten cables that you see here, and most often associated with the distal end, down at the working end of the device. But that's always referring to something with the cable portion itself, not the rods, but the cable portion.

Q. And if we could just briefly go over to the other/distal end.

That's -- can you explain what you see there?

A. Yeah. So this is a particular type of tool, a particular model here that's being shown. And the length of flexible cable, then, is coming from the rod and going through pulleys,

some different pulleys here to allow that movement to take place here at this end of the device. So it's -- it's the place where that rotary input from the motor gets trans-- transferred to some type of a specific movement, a pitch or -- or the grip and operation, yaw and grip-type operation, then. That's where it occurs, is down here.

Q. And when you hear about failure mode such as cable breakage or cable tension in the context of your investigation, what do you understand that to be referring to at the distal end here?

A. It's typically referring to somewhere in this area, where the cable goes around a pulley or where it's exposed in some way, so it's typically down here at this end.

Q. What information have you seen in your investigation about failure of the rods that connect between those two cable portions at the ends?

A. I don't think I've ever seen an occasion where it was indicated that the rod was a problem, that the rod had failed for some reason. I don't think -- I don't recall ever seeing that.

Q. And if we could move up to the -- to the first instrument from the bottom and zoom in on the housing.

As to the cables on the proximal end, where would those be within this, what we see here?

A. They are coming out of that -- that shaft that goes off to

the left side and goes down to the distal end. They're coming off of that, typically route around a pulley of some sort, a drive pulley of some sort, and then are attached to this input drive mechanism up here. So there's four of these inputs here.

And you -- you see it, maybe not so clearly in this, but there are four of these locations where that cable is going to terminate and be attached so that -- so that the rotary motion here will transfer into motion down through the rod and to the distal end of the tool.

MR. VAN HOVEN: Could we go to Slide 12?

Q. What is this showing, Dr. Parnell?

A. This is showing a particular EndoWrist. The housing cover is removed and it's put into a fixture, a specific fixture that clamps and holds it, positions it. This -- this would be one of the fixtures that is associated with adjustment of cable.

Q. And we'll talk about the process a little bit later. I want to focus on just the EndoWrist itself and its -- kind of its components.

MR. VAN HOVEN: Could we go to Slide 11 and focus on the left side image?

Q. So those -- the cables that we were talking about that connect from the end of the rods, can you explain how they connect to the disks that turn and interface with the robot arm motor?

A. Yeah. There's basically an attachment here that clamps

the cable into that rotary portion that we talked about so that the -- so that the input from the robot at the underside, where it attaches to the robot, will rotate, this -- this portion that you see here. You're seeing two of them, the two that are on the side closest.

And so it will turn that, which, in turn, moves the cable then, moves it back and forth. It can go clockwise and counterclockwise.

MR. VAN HOVEN: And could we zoom in even more on, I guess, the silver-looking components that have the screws or bolts on them?

Q. And what are we seeing here with respect to the cables and their attachment?

A. You're seeing attachment and basically kind of a clamping mechanism that's used to clamp the cable to this input drive post.

Q. And is this -- is this visible in this manner within the Rebotix facility during their processes?

A. Yes, with that cover of the -- of this end of the device taken off, this is what you would see, yes.

MR. VAN HOVEN: Your Honor, it's 11:59. I'd be moving on to something pretty much completely new here.

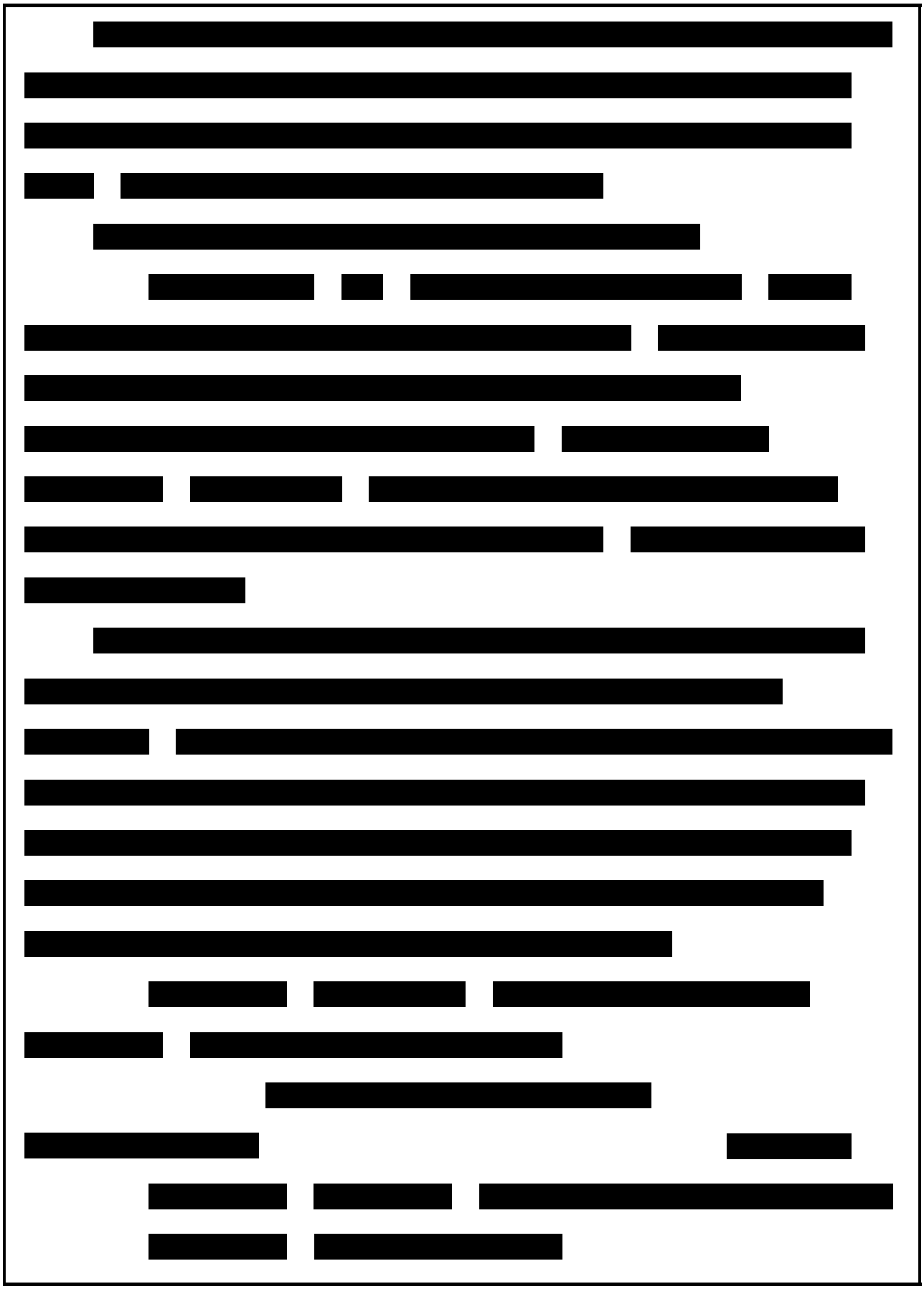
THE COURT: Sounds like a good place to break. Thank you, Mr. Van Hoven.

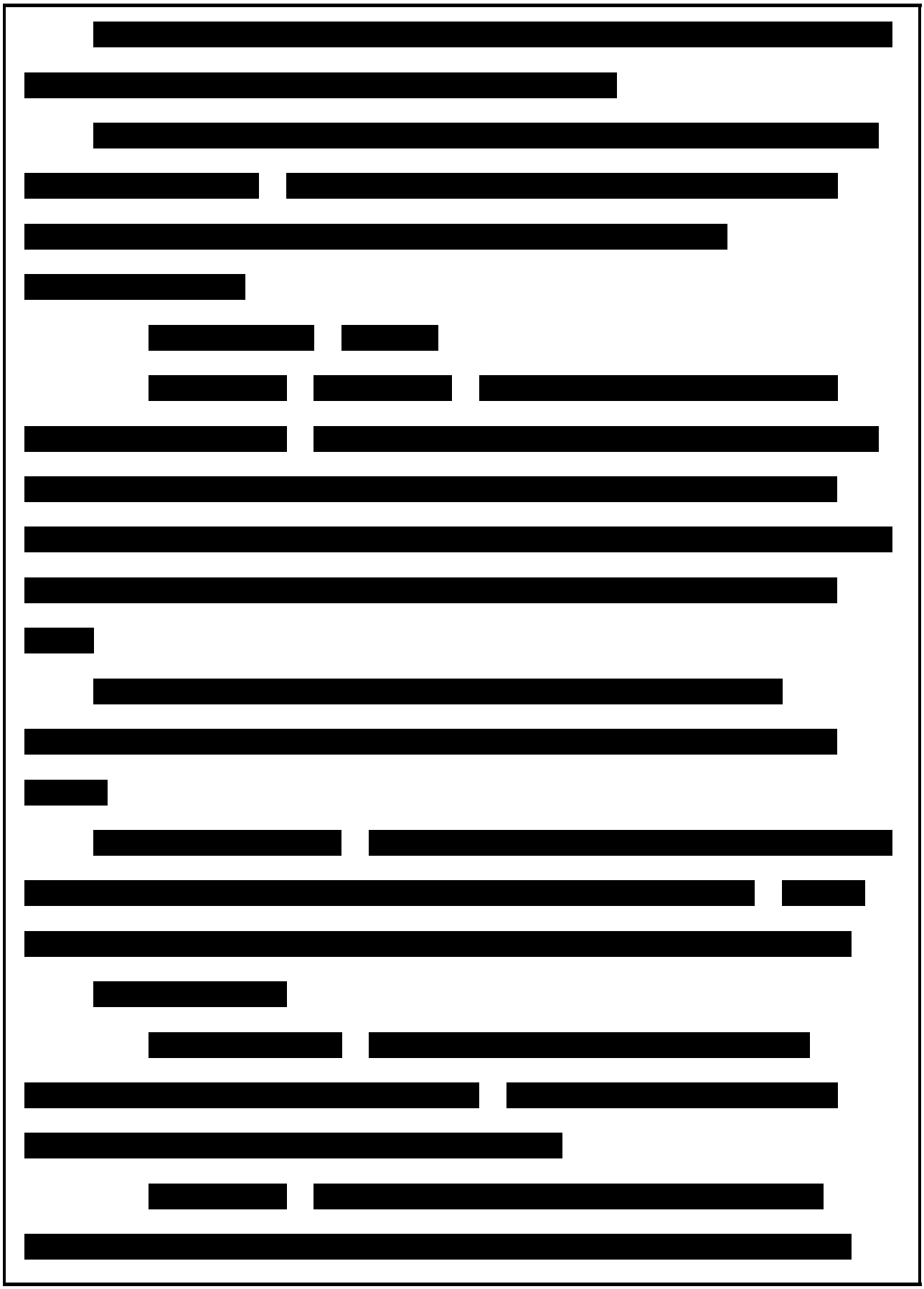
Folks, let's I want to make sure that staff also get a

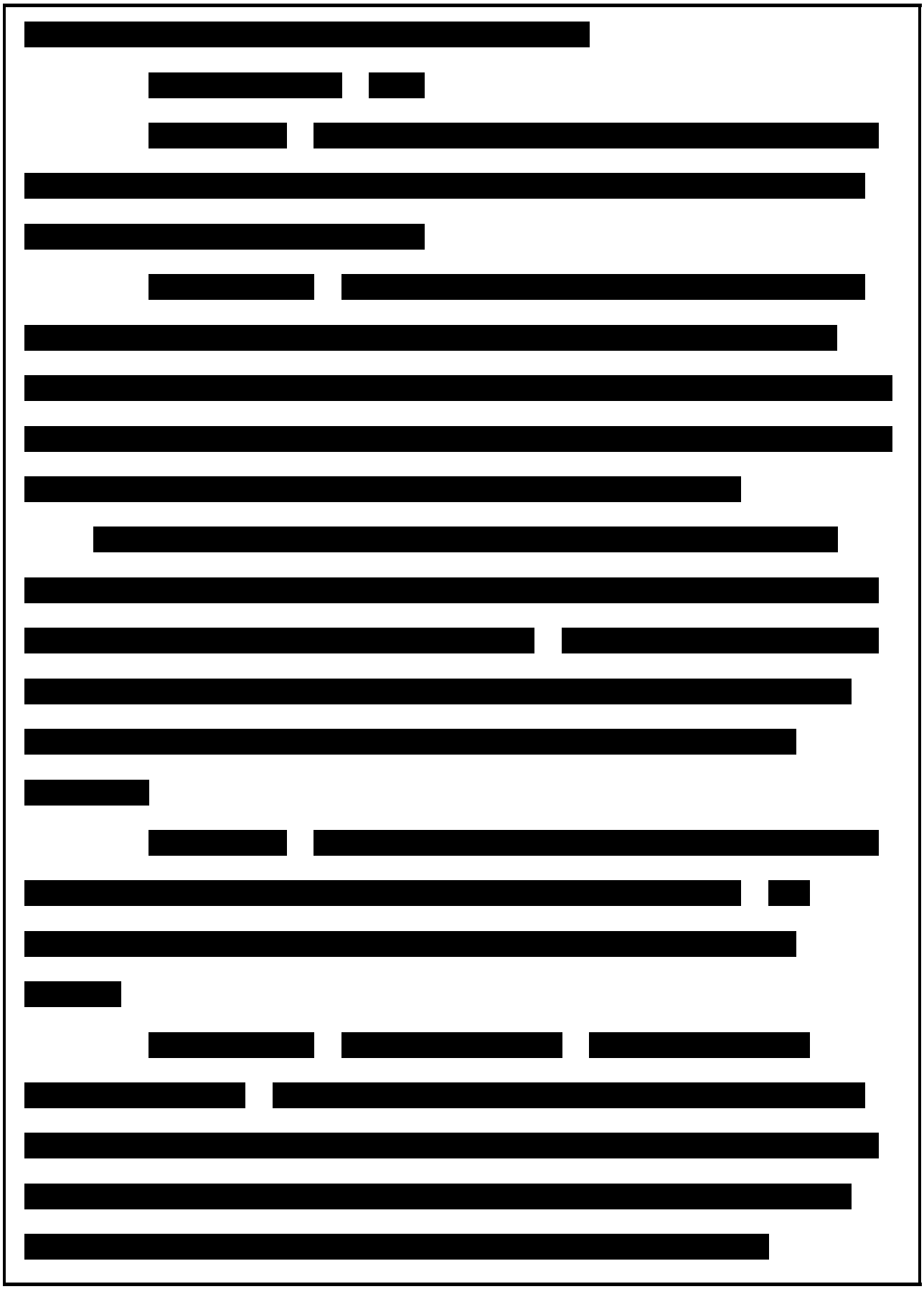
good break here. So why don't we plan to get back in about 45 minutes. So we'll expect you back here at 12:45; all right?

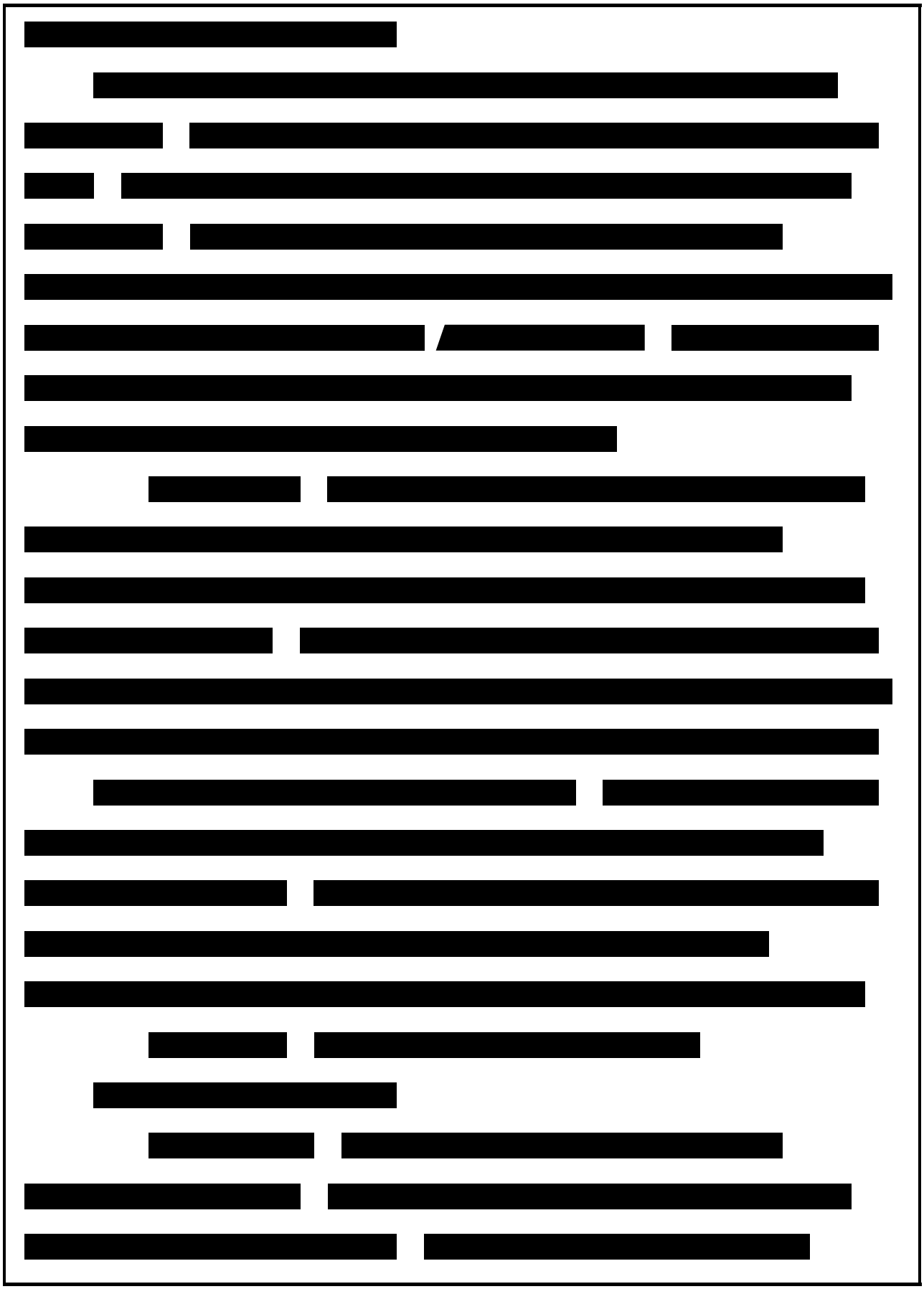
All rise for the jury.

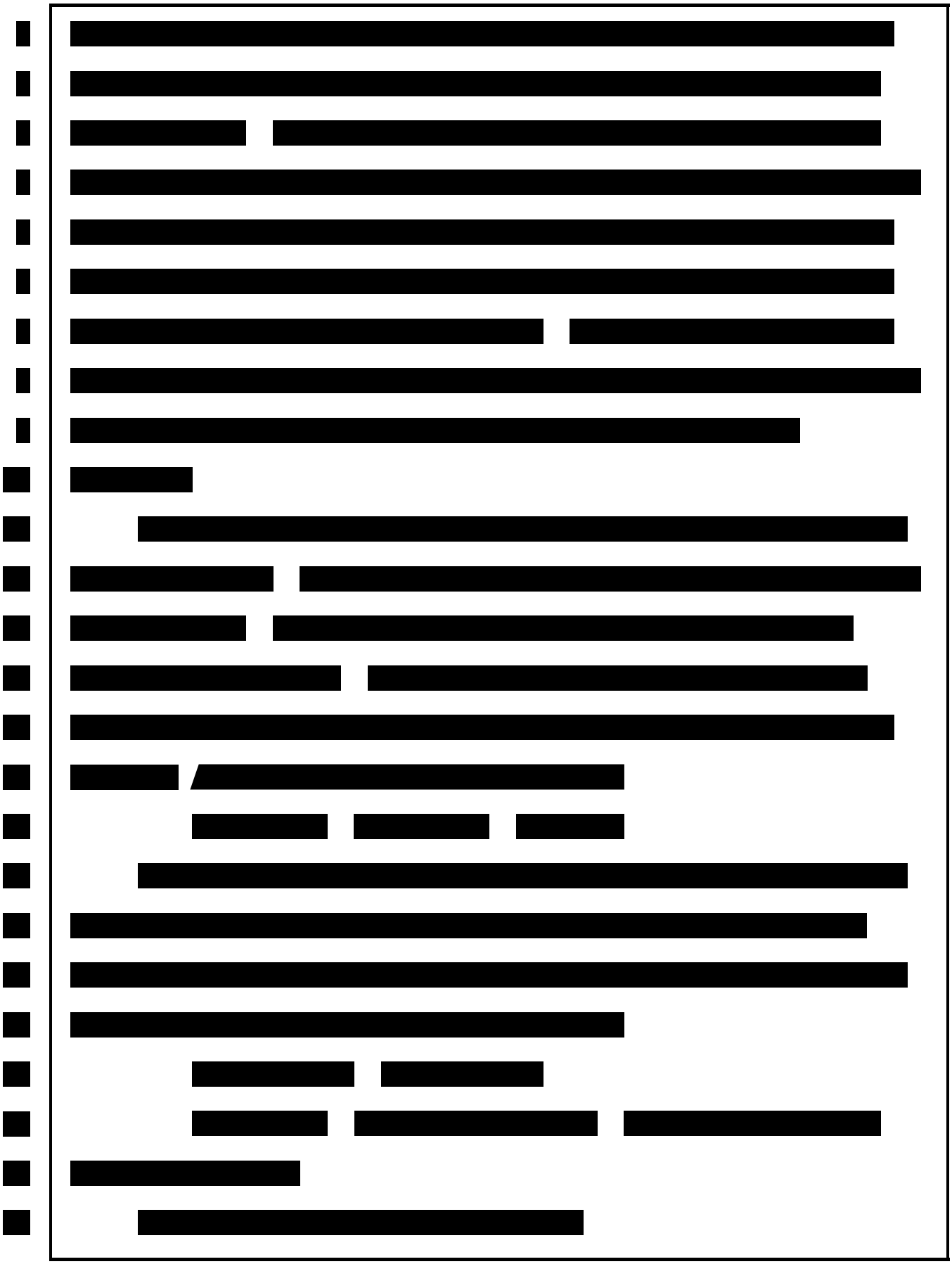
(The jury leaves the courtroom.)











(The jury enters the courtroom.)

(Proceedings were heard in the presence of the jury.)

THE COURT: You may be seated.

MR. VAN HOVEN: Could we bring that back up, the demonstratives? And go to Slide 3.

BY MR. VAN HOVEN:

Q. Dr. Parnell, you could see, on that first bullet point, it discusses reviewed Rebotix documentation and independent certifications underlying Rebotix SIS service procedure?

A. Yes.

Q. What activities did you undertake related to that bullet point?

A. That's really associated with all of the procedures that

were developed to provide kind of the roadmap through the service procedure, so specifications that were developed, procedures, steps that were spelled out to carry out the service procedure.

And then there were also some independent certifications that were performed outside of Rebotix's quality review types of certifications.

Q. And there's a bullet point: Personally inspected Rebotix facility on August 10, 2021. What are you referring -- what's being referred to there?

A. That's the visit to the Rebotix facility in Florida that we were talking about. We talked about some of the aspects of it earlier. And that's the date that I was present there.

Q. Did you take new pictures while you were there?

A. Yes, I did.

Q. And based on that documentation and your visit, what does bullet point three mean to you?

A. Well, through what I saw firsthand, talking to Rebotix staff, like Mr. Fiegel, and then going through Rebotix's service procedures, you know, I was able to conclude that they had a process that was thorough and I felt it was a reliable process for performing the service.

Q. Let's go to Slide 4. And this is fairly dense but can you generally describe what this is?

A. Yeah. This is a wall chart that was at the Rebotix

facility; and it's associated with cleaning processes of the devices, both on the initial or incoming side and then on the outgoing side, after the service procedure is carried out with the final cleaning and lubrication steps -- are before a device would be shipped out.

Q. And what's your understanding of who would refer to a document like this?

A. A technician that's preparing to do service procedure, for example, would -- would take a given device, each given device, each EndoWrist, would go through these cleaning steps and -- before starting.

Q. And let's go to Slide 7. Is this an image that you took on your visit to Rebotix?

A. Yes, it is.

Q. What is that showing?

A. So, really, first step after -- after cleaning, each device undergoes a very careful visual inspection. Magnification is used, looking at the device, trying to identify if there's any sort of damage or issue that the -- that would screen the device out so that it wouldn't be a candidate to go through the service procedure then.

And so this is one particular device that had damage to the cables, so that's what you see here. This is down at the distal end. There is an area where you can see damage. One cable is actually broken, one that's got a frayed area, then.

So this would be an EndoWrist that would not be a candidate for going through the repair procedure because, you know, parts like this are not -- are not replaced. The service procedure has a number of steps after the inspection; but they are adjustment types of steps, cable adjustment, scissors sharpening, if need be, so things that are identified are performed, but there are not components that are being replaced.

Q. And from what you saw at Rebotix, who is performing this sort of visual inspection?

A. This would typically be done by a staff member, possibly a technician. I mean, when I was there, Greg Fiegel was showing me the process steps; but it would more typically be done by a trained technician, to go through these steps.

[redacted]

BY MR. VAN HOVEN:

Q. Do they have anything available to them to facilitate this visual inspection?

A. Yes, they do. Things like optical microscopes to allow

for looking at -- at areas in detail to be able to more clearly see detail on items like this.

So this is a photo with magnification.

Q. Are you aware of any other reference that may be available to someone performing this visual inspection under the Rebotix procedure?

A. I'm not quite sure what you mean there.

Q. Anything that -- anything that's available for the technician to reference?

A. Well, the procedural documents that I mentioned are available. The procedural documents provide essentially kind of a roadmap or a guide through the series of steps. And each one references particular steps and operations to perform.

MR. VAN HOVEN: Let's go to Slide 10, please.

BY MR. VAN HOVEN:

Q. What is this machine that we see here, Dr. Parnell?

A. Yeah. This is a piece of test equipment. So some of the EndoWrists are referred to as electrosurgical types of instruments. So they provide electrical signal to the end of the instrument. And you'll see terms like "monopolar" or "bipolar" depending on the type of action that's performed.

And so, this piece of equipment is called -- associated with a hipot test. This is to assess and confirm the insulation, that insulation is intact on the device.

And so this -- when you connect or set up this instrument

to perform the tests on the electrosurgical instruments, you come away with either a pass or a fail. And you see up here on the screen, in the upper part, this one is pass. So this is indicating that insulation of the device is intact and not screened out.

If there was a problem here, this would be another factor that could screen out a device that would not make it a candidate for service.

MR. VAN HOVEN: Slide 11, please.

BY MR. VAN HOVEN:

Q. Dr. Parnell, what are we looking at here?

A. Here you're looking at an EndoWrist that's mounted in a fixture. So there's some fixtures that are utilized for different parts of the process, and this is associated with the cable adjustment and tensioning process.

Another photo that I took in August 2021, when I was there, this fixture basically mounts the EndoWrist and allows the tool end, the distal end, to be held in a neutral position to facilitate the cable process.

Q. Could you elaborate a little bit on that? What do you mean held in a neutral position?

A. It's -- it's at the end of the -- the tool. It's -- its position.

You know, no -- no roll, no rotation. The components are closed, no pitch. So it's basically in kind of the zero

position, the no -- no movement position, then, to provide the reference.

Q. And how does that facilitate cable adjustment and tensioning?

A. Well, it's to get the device into that, you know, neutral position to facilitate the process from there. So it's -- like I said, it's a reference position.

Q. As we --

MR. VAN HOVEN: Can we go to Slide 13?

Q. And this is showing, a little closer, what's on the proximal housing side. And, you know, looking at this, could you describe to the jury what's involved in tensioning the cables, where that happens?

A. Yeah. So it happens back at this end, at the proximal end of the device. Those fastening screws are loosened and the cable can be adjusted from that point. And there -- like I said, there's a procedure to follow to carry that out. But back here is where it happens on each of the four drive.

Q. In addition to the cable tensioning process, are there other operations that may be performed on an EndoWrist instrument in the Rebotix repair process?

A. Yes, there are.

Q. What are some of those?

A. Well, for example, I mentioned that in the inspection, you might determine that there was a problem with instruments that

are designed to grasp tissue, for example, and that those operating components need to be able to meet properly so that they can grasp tissue. Sometimes there's -- there's some damage there that maybe can be -- can be rectified during the service process by straightening the tool to allow the ends to come together again.

Another one would be scissors that are not sharp or -- so they're not cutting properly, or maybe haven't -- have a nick on the blade, something like that, something that's causing either an alignment or an issue with performing their cutting operation.

So things like that are part of steps that are -- would be taken during service procedure to rectify.

Q. And after the various repair steps are performed, is there anything else; do they do anything else in the Rebotix procedure?

A. After -- after repair steps are performed, then there's an evaluation of each of those. Now is -- now is the device functioning appropriately as expected? Are you getting this direct one-to-one motion at the distal end from the inputs?

There's also a step that's associated with kind of a validation on cable tension. It's called checking the free end torque. So there's a table for each instrument and each one of these degrees of freedom that provides a torque range, a load range that the instrument should have after adjustment of the

cables. And, you know, between visual inspection of the movement and this free end torque, this is effectively confirmation that you've adjusted into the proper range and --

Q. And, Dr. Parnell, you talked about that being performed for the degrees of freedom. Could you maybe explain that a little more in layman terms, what you mean by the degrees of freedom?

A. Basically, each one of these input wheels, input tabs, that mount to the robot are controlling a particular degree of freedom down at the distal end, down at the wrist end.

And as I mentioned, effectively, there's four. There's pitch, there's roll at the end, and then there are the two yaw degrees of freedom, or sometimes it's referred to as yaw and grip. But they're basically a thing that will actuate to bring together to grasp tissue or to cut or something like that. That's the part that carries out that step. And the other is essentially more -- more positioning, I would say.

But each one of those is controlled by an input, by a motor on the robot and is carried, through rotation, back here at this end.

Q. And so each of those is tested in that process after tensioning; is that right?

A. Yes, that's right.

MR. VAN HOVEN: Counsel, any objections to 783R?

MS. PARKER: No objection to 783R.

MR. VAN HOVEN: Can we bring up 783R, Bobby?

THE COURT: Move for admission, please, Mr. Van Hoven?

MR. VAN HOVEN: I apologize. Move to admit 783R and publish to the jury.

THE COURT: It's admitted and may be published.

(Trial Exhibit 783R received in evidence.)

MR. VAN HOVEN: And maybe zoom in on the top third of the document or so.

MS. PARKER: I'm sorry, counsel. I don't believe this is 783R, based on the exhibit sticker on the cover.

MR. VAN HOVEN: Okay. That's what I have. I'd hold off on that. I'll send that to the tech.

BY MR. VAN HOVEN:

Q. Dr. Parnell, we talked about the process, the repair process you saw at Rebotix, but did you do any investigation into how that process was created?

A. Yes, I did.

Q. And can you briefly describe the materials you consulted in doing that investigation?

A. Well, both -- beyond discussions with Rebotix personnel like Greg Fiegel during my visit, beyond that, then, is looking at documents that were created to define each of the process steps and ones that were defined to basically describe the specifications, like how -- how far the tool should open and close, things like that, things that put movement and

dimensional type of specifications on each of the different EndoWrists.

Q. And to your understanding, what is that process called of creating those kind of documents?

A. So this is along the lines of what we talked about as reverse-engineering. So you've got -- you've got a component and you are carrying out tests and measurements to define specifications associated with it, to be able to extract or develop dimensions and movements and things like that that are correct for that particular product, then.

MR. VAN HOVEN: And I believe it's admitted but can we republish 783R?

THE COURT: You may.

MR. VAN HOVEN: We'll continue until that pops up.

BY MR. VAN HOVEN:

Q. Do you have any understanding of any testing that Rebotix may have performed on the instruments or on its process?

A. I'm not sure. Are you referring to certification steps, that kind of thing, or something else?

Q. Actually, I'm referring to instruments that were repaired using their process, any testing they did after the instruments went through the process.

A. Yeah. So -- so after -- after it goes through the process, then there are tests basically to evaluate that function.

Now, am I -- is the instrument providing the movement that is -- is specified for that device? As I mentioned also, the steps involving checking free end torque, that they're within the specified range of each degree of freedom, both in clockwise and counterclockwise movements.

So each of the things that are evaluated on the incoming side are also evaluated before it would go out. And if there was still -- if there was something that is not in the specified range, then it might go through the service process steps again to take -- to rectify that.

Q. And we have the elusive 783R up on the screen.

MR. VAN HOVEN: If we could look at the top, about, third of this document.

BY MR. VAN HOVEN:

Q. Could you take a look and explain to the jury what type of document this is?

A. So this is a product specification associated with a particular type of EndoWrist. Up there in the title, you see it's the EndoWrist reference 420205, so that's a model number. Each one of these different EndoWrists has a model number and then the name of this particular one is a fenestrated bipolar forceps. So this is one that does have an electro function like we were talking about before. This is bipolar.

Q. And is it your understanding that there would be similar documents for other types of EndoWrists?

A. Yes. Similar ones that reference process steps in the service procedure. This is kind of a step by step through for a particular device type.

MR. VAN HOVEN: And can we go to page 6? And highlight section 5.4 and 5.41.

BY MR. VAN HOVEN:

Q. Dr. Parnell, can you take a look at this and explain to the jury what that's describing to you at least?

A. Yeah. So this is basically just saying that the documentation is going to be in their standard Rebotix format. Risk management process is associated with a particular risk management procedure that they have in place and there's an SOP-1006. So that's a document reference and that's a reference to the risk management procedure.

Q. And if you -- we'll hit just little snippets here. We don't want to go through the whole thing.

MR. VAN HOVEN: But can we look at, also on page 6, under Number 6.

Q. Could you read that and provide your understanding to the jury?

A. Yeah. So this section starts out on physical characteristics, physical characteristics recovered, remaining uses.

So it just states kind of the criteria for the use counter in order to go through the service procedure; that in order for

it to be a candidate for the service procedure, it needs to have at least one original remaining use on the use counter.

It can't be a zero. If it's zero, it's totally expired and could not be reset or serviced in that way.

So an original expired device, 10 uses, cannot be updated. So that's what it's stating. So you need to have one.

Typically they specify that the desirable is to have one use remaining, then.

MR. VAN HOVEN: And could we go to the bottom of page 8? This is under Section 7, Performance Characteristics, that final, that final part.

Q. And, again, we don't want to go through the whole thing, but this is an example. Would you explain to the jury what this is describing as far as performance characteristics?

A. Yeah. So this is talking about movements associated with a life test cycle, so a testing cycle that they have performed as kind of a step to qualify their service procedure from a testing point of view.

And so what are the steps that take place then? That goes through each of the types of movements associated to the maximum movement in each direction. And so there will be a -- like, for example, first one is pitch up to maximum host system position. And there will be a -- effectively, a dimension associated with that in terms of what will be happening at the tool end for each one.

And as I said, this was part of a -- kind of the life test type of specification, so they used chicken breast as the tissue surrogate to be able to go through their testing procedure here.

Q. And I'm sorry, what do you mean when you're talking about a Rebotix life test?

A. Rebotix did life testing after developing their -- their process, their procedure.

And so they identified specific instrument types. The objective is to identify kind of worst-case instrument in each category, whether it's one with scissors, whether it's one with an electro -- a capability like this one, the bipolar device.

And they went through a series of test steps basically as a way to qualify a device after it's gone through the service procedure.

MR. VAN HOVEN: Can we go to Slide 17, at the bottom paragraph, and image -- I'm sorry, of 783R. We're still on 783R, the bottom paragraph and image.

BY MR. VAN HOVEN:

Q. Can you take a look at that, Dr. Parnell, and explain to the jury what we're seeing in this Rebotix document?

A. Yes. So it talked about the four different degrees of freedom that are here. These are the mounting tabs that mount to the -- to the robot. Each of these disks is a place that has a motor to drive it, to be able to turn it, in clockwise or

counterclockwise direction. These are each of the 4 degrees of freedom, then. So upper left is yaw, here yaw one, yaw two. Below, yaw grip, you'll see referred to sometimes. And then third one in the upper right is a pitch and then a rotation, turning rotation of the shaft of the device.

And this portion of the document is starting out to talk about what I referred to a little bit earlier as part of the test after this service procedure.

So each of these degrees of freedom has a no-load torque. No load at the tool end, but how much torque is required to turn it in both directions. And this is part of the evaluation that cable tension is in the right range, then. So there's a range on the torque level that's measured here.

Let's see. Yeah. I think that described it. The figures, for reference, of specific degrees freedom and then each of these, there would be a series of these steps that will define this level, this no-load torque for each degree of freedom. There's a table that this document comes from where all the different types of devices and the different degrees of freedom each have a range associated on that table.

One other thing to point out here is that there is a difference in the no-load torque associated with clockwise versus counterclockwise. Just something to note.

MR. VAN HOVEN: Is there no objection to SIS095115?

MS. PARKER: Do we have an exhibit number?

MR. VAN HOVEN: Yeah, TX0136.

MS. PARKER: 136R is already admitted, so no objection there.

MR. VAN HOVEN: Could we bring up 136R, please.

BY MR. VAN HOVEN:

Q. Dr. Parnell, are you -- do you have some knowledge of the relationship between Rebotix and SIS?

A. Yes. There was a -- a business relationship between the companies over long term.

Q. And did you have any discussions with anyone in SIS -- with SIS in preparing your report?

A. Yes. During the time of this engagement, I did have discussion with Mr. Posdal.

Q. And did you review some SIS documents in preparing your report?

A. Yes, I did.

MR. VAN HOVEN: Could we go to page 5 of Trial Exhibit 136R?

Q. And, Dr. Parnell, have you seen a document like this, where Surgical Instrument Service Company is providing information about its EndoWrist repairs?

A. Yes, I have.

MR. VAN HOVEN: And could we go to page 8 of that document?

Q. And this is from the SIS document, but do you have an

understanding of what this is depicting?

A. Yes. This is, basically, kind of a high-level flow chart to guide through the process, the service process steps, then showing what those process steps entail, what kind of things are done. Some things that are -- can be specific to a certain type of device. You'll see there's one associated with the electrosurgical testing like we talked about before.

So it's really kind of a -- kind of a flow chart to -- to provide some guidance through the overall process.

Q. And if you know, how does this correspond to the Rebotix process that you've reviewed in person and via documentation?

A. Yeah. So Rebotix has a similar type of flow chart that maybe this -- more detailed, it refers to specific process documents. This is more of a high-level -- more of a high-level flow chart, or roadmap, I would say.

So there's not -- there's not reference to specific process documents, but there's the description in the name of the steps. And so that's where the reference would come in.

[redacted]

BY MR. VAN HOVEN:

Q. How does -- how does this document, the steps here,

compare to what you saw in both documentation and your in-person visit at Rebotix?

A. This, again, is a high-level step or roadmap through that. And so the basic steps or blocks are similar. They'll -- they would have a correspondence to Rebotix's process steps.

MR. VAN HOVEN: Could we move back to the demonstratives, to Slide 17?

BY MR. VAN HOVEN:

Q. I'd like to change gears here and talk a little bit about Intuitive's interactions with the Rebotix process; okay?

A. All right.

Q. So the title of the slide is "Intuitive Did Not Test Serviced EndoWrists."

What's your understanding of that?

A. That Intuitive did not test EndoWrists like they had gone through the Rebotix process steps, the service process steps.

Q. And so the first sub bullet point there is: Did not conduct its own testing on the feasibility of servicing EndoWrists.

What is meant there?

A. That Intuitive did not conduct testing on these types of serviced EndoWrists or didn't do it on their own, didn't do testing, you know, extensive testing like life testing or things like that on devices from Rebotix, that had gone through the Rebotix process.

Q. And you also noted that the -- didn't test EndoWrists serviced by Rebotix or other ISOs. What did you mean by that?

A. Similar to that there was not detailed testing done on these devices. There were some devices that had been inspected through our RMA type of returns, but there wasn't a test or evaluation type of a program that was undertaken on these devices.

Q. What do you mean there were devices that were looked at through RMA concerns at Intuitive?

A. These would be -- you know, these RMAs are the big collection of devices that were returned to Intuitive. So, you know, they're mostly Intuitive devices without any Rebotix service, but some were flagged as being devices that were serviced by a third party like Rebotix. And so -- and that's all I meant, that some of these devices are examined, there's comments that are provided from that RMA examination.

Q. How do you consider that different than performing testing? How do you consider the RMA evaluation different from performing testing, if at all?

A. I mean, there you're basically looking at a given device and it's returned for some reason. You know, typically, you wouldn't be able to continue to run operations with that device to evaluate it. Typically, it's got -- there's some sort of issue that's -- that's occurred, something -- there's misuse, there's damage. There's something that caused it to be

returned through the RMA process.

Q. And then there's a final point about, "Did not determine whether EndoWrists returned through the RMA process experienced failure caused by the Rebotix service procedure."

What do you mean by that?

A. As I said, so devices are examined and, through that examination, you can -- or Intuitive could determine if it was a device that had been serviced, meaning gone through this service procedure, had the use counter reset, then through that process.

And so we're -- we're just talking here about -- yeah, really some of the specific process -- specific devices in that RMA. Some don't have any kind of note associated with a service procedure. And so particularly, we're looking at some specific RMAs associated with that that did not have any indication of even whether it was a serviced device and that the service process led to -- what was the cause of an issue with the device.

Q. And how was that RMA data presented?

A. It will be presented different ways. You may see -- you may see counts or summaries of -- for different EndoWrist types, how many came back through RMAs. But there's a -- a very detailed spreadsheet associated with RMAs over a period of time. And those typically got a more detailed inspection and review to assess what the particular issue was and to make a

comment on what caused that issue or what was believed to cause the issue.

And it might be something like -- one comment that I looked at was associated with, you know, this is most commonly caused by misuse and excessive force at the distal end.

So there could be different types of comments based on what was examined and what the RMA tech was determining from the inspection.

Q. And have you looked at any of those entries for any specific EndoWrist RMAs?

A. Yes, I did.

Q. What was the source of the information for that look-up exercise?

A. One that I was asked to look at was associated with a set of four RMAs that were on the opening Intuitive slides, that were flagged through that on an opening slide.

Q. And what did you discover through that investigation?

A. The specific four that were called out there, there were some things that I think were important to look at. One was, on those four, there was no injury or death associated with the particular device, with that particular EndoWrist.

But the other part that was interesting was in the very detailed inspection and observation notes -- was that there was nothing actually to indicate there that it was a Rebotix service process. There was no note on having the chip added

for reset as you see in some other places.

But the really -- one really interesting point was the observation was made by the inspector that the type of damage that was observed on these four, he said, was most typically caused by misuse of the device, that it was caused by having excessive force applied at this distal end of the device.

So it was a -- it was characterized by Intuitive inspection as being a misuse type of issue.

MR. VAN HOVEN: Could we go to Slide 14?

THE COURT: Mr. Van Hoven, are you nearing --

MR. VAN HOVEN: I'm starting something new, so...

THE COURT: Let's take five minutes and come back.

All rise for the jury.

(The jury leaves the courtroom.)

[redacted]

(The jury enters the courtroom.)

(Proceedings were heard in the presence of the jury.)

THE COURT: You may be seated.

MR. VAN HOVEN: Could we go back to Slide 14 of the demonstratives.

BY MR. VAN HOVEN:

[redacted]

BY MR. VAN HOVEN:

Q. What is the -- what are you referring to in the title of that slide?

A. Basically, kind of an overview conclusion, that there is no really useful information that comes from the use counter, nothing on condition of the instrument.

Q. And you have a few sub bullet points. What are you referring to with the first bullet point?

A. That the use counter only measures how many times an EndoWrist was used for a surgical operation, nothing about the time or complexity or any of the details associated with it.

I sometimes think of an analogy as being that the use counter is kind of similar to your car. If you looked at how many times your car was started, but you didn't look at all at whether you're driving cross country or whether you're driving locally, it's kind of the same here. There's nothing about the conditions of use or the length of use or anything beyond just that it was used.

Q. And, Dr. Parnell, what are you referring to in the second

sub bullet point there?

A. Another thing that is not done -- is not provided from the use counter is any mishandling or misuse is not recorded or taken account of in the use counter. So if there's some type of physical damage that takes place, then that's not included in the use counter.

Q. And those first two bullet points, how do those relate to the actual failure modes of the instruments that you have observed?

A. Generally, the use counter doesn't really tell you anything about the -- the failure mode, if there was one or anything like that. It would just give you a count as to when it occurred if it was -- if it occurred during a specific use.

But there's no other info that it gives you related to the particular application, the particular procedure that it went through.

Q. What is being referred to in that third bullet point, Dr. Parnell? Could you explain that to the jury?

A. So from Intuitive documents that I reviewed and testimony, staff testimony that I reviewed, it was stated that -- how did we come to the 10-use limit? And it was stated in there that it came as a goal or a target from marketing department that we're going to use a 10-use limit.

But then it was -- engineering was asked to validate, to test if EndoWrists could indeed perform reliably up to 10 uses.

But it's a -- it's a target and then a validation of that target, not can it go for more uses than 10. They tested with the goal or the objective to validate that 10 was an acceptable limit, that it could perform reliably up to 10.

Q. And are you aware, and I -- you note 10 there. Are you aware of some Intuitive instruments having different use limit numbers?

A. Yes.

Q. Explain that to the jury, please.

A. There -- the -- the majority of the Si instruments started out with having 10. There's some -- there's some particular instrument types that had different numbers, but most fell under this 10-use limit type of setup and were validated with that limit in mind.

[redacted]

BY MR. VAN HOVEN:

Q. And you -- I believe you mentioned that there were some instruments that had different than a 10-use limit. Do you have any understanding as to those circumstances and what that involved?

A. I don't know if -- if there was an extended use program

that was undertaken on the Xi instruments a few years ago. So after EndoWrists had been in use for long period -- for a number of years, for a long period of time, then there was an extended use program that was undertaken to explore some higher number of uses, if it was feasible for some of the devices.

Q. The final bullet point there says: It does not track condition of the instrument.

What are you referring to there?

A. The types of things that I talked about, it doesn't indicate if there is damage or the condition of the instrument -- actually, even if it's still functional, for that matter. It's really just that the proximal end of the device with the chip can be mounted to the robot, but it might not be operational. That has to be determined by inspection. The use counter doesn't tell you that type of thing.

MR. VAN HOVEN: Slide 15.

BY MR. VAN HOVEN:

Q. And could you look at this slide and, generally, explain to the jury what's been conveyed here?

A. Yeah. So this slide is just detailing some of the -- some of the types of things that we talked about that is not information that's a part of the use counter. So it just breaks it down a little bit more, like time of use; there's no information on time of use. Or there's no information on specific movements and how many there were in a given use.

Or the types of procedures that it was utilized in, or the forces involved, you know, in terms of the torque or movement or any types of things like that.

And no information if there was a malfunction of some sort or if an instrument was misused or abused in some way.

None of those things are part of the use counter. The use counter is a very simple thing in terms of what is counted there.

Q. To your knowledge, does Intuitive have available to it information from which it could determine some of this information?

A. Yes. I did see testimony that in some cases, in terms of investigation of a return, that there's some fairly detailed logs that are explored, but they're not part of the use counter. That's information that comes through a different mechanism; and that does include more -- more -- you might consider kind of a detailed log of operations that were taking place and torques that were involved during those operations as kind of, really, a log of the action for that particular activity, for that particular use then, but as separate from the use counter. It's not a part of the use counter.

MR. VAN HOVEN: Is there any objection to Trial Exhibit 281?

MS. PARKER: No objection.

MR. VAN HOVEN: We move to admit Trial Exhibit 281.

THE COURT: It's admitted.

(Trial Exhibit 281 received in evidence.)

MR. VAN HOVEN: May we publish it to the jury?

THE COURT: You may.

MR. VAN HOVEN: If we could zoom in on the top of the slide.

BY MR. VAN HOVEN:

Q. Dr. Parnell, is this a document that you have seen before?

A. Yes. It is a document I've seen before. Title is "RMA Analysis for Possible Life Extension," and this part of the study was done in the 2017 to 2018 time frame.

Q. Could you remind us again what RMA stands for?

A. Return material authorization. It's basically a return of an EndoWrist that's -- had some sort of issue that the customer has identified and so it's returned back to Intuitive.

MR. VAN HOVEN: Page 4, please.

Q. I guess, generally, do you have an understanding of what this slide is depicting?

A. Yes. There are six specific types of EndoWrists that their number of RMAs, number of returns, are being counted here. So each one of these curves pertains to a particular EndoWrist. And that number over on the right side, that links to the model or the specification, and, you know, will have a certain designation as to what that particular EndoWrist is. That's what each of these curves then represents, the number of

returns for each number of lives that have been used, so it starts at zero, goes one -- goes through 10.

So this is -- that's what's on the X, or the horizontal axis, is how many lives are used. And the Y value is how many RMA returns there were with one use, used, for example, and then two, and then three, et cetera.

Q. From reviewing this slide, do you have any opinions as to what's represented by the patterns of the data in this RMA slide?

A. Yes. There's some observations that are interesting. On the one that's the upper curve that has the greatest number of RMAs returned, one thing that's interesting is that after about two to three uses, that the number returned is fairly, fairly constant. It's not increasing significantly from there out, that it sort of -- sort of reaches a steady state value, if you will, where the number returned stays fairly flat fairly straight from there on.

The next one down, kind of a similar observation. The ones at the lower part, there's fewer RMAs, you know. It's a little harder to see from the curves themselves; but when you look to the data, a similar thing is taking place. It kind of flattens out and doesn't increase with number -- with the number of uses to any significant degree.

MR. VAN HOVEN: Slide 6, please.

\\\

BY MR. VAN HOVEN:

Q. Could you describe what we're seeing on this slide?

A. Yes. So this is taking the data that went into the plot that we just looked at and combining the data point in a little bit different way.

So each one of these symbols on its curve is basically the sum of the failures that have occurred prior to that, the sum of the RMAs that have occurred prior to that.

And to me, what this shows is that if there was -- if there was significant increase with the number of lives used on the use counter, you'd start to see this curve kind of really tail up then.

But each one of these curves becomes quite linear so that there's not a significant increase with number of lives used as you plot the data in this fashion.

MR. VAN HOVEN: We're almost done, Your Honor. Can we have one minute, please.

THE COURT: You can have it.

(Conferring.)

MR. VAN HOVEN: Is there any objection to Trial Exhibit 572?

MS. PARKER: No objection.

MR. VAN HOVEN: Move to admit Trial Exhibit 572.

THE COURT: It can be admitted.

MR. VAN HOVEN: And publish it to the jury.

THE COURT: By all means.

(Trial Exhibit 572 received in evidence.)

MR. VAN HOVEN: And maybe get the top third in the blowup. A little further, down through Purpose. There we go.

BY MR. VAN HOVEN:

Q. Dr. Parnell, do you have an understanding of what this document is?

A. Yes. This is a report on some early life testing that was done. This would have been on Si -- a particular Si type of instrument. And this indicates it was done in September to October 2009.

Q. Do you have an understanding as to how Intuitive performs this life testing generally on EndoWrist instruments?

A. Yes, I do.

Q. What is this -- could you explain that to the jury?

A. They have a life test protocol called out, so it's sometimes referred to as simulated surgical use. So it's done with kind of a recipe or specification for number of movements and activities that are going to take place in each degree of freedom to represent a particular use. So it's got a recipe that is followed for that. And in between each use, there is a cleaning -- or sometimes called reprocessing -- step that takes place then.

Q. Could we go then -- and are you aware with -- of how that testing is carried out with respect to the rated lives of the

instrument?

A. Yes. As I mentioned before, tests here at this stage were done to -- with the intent to validate a set number of lives.

So these are not going to be tested to failure, but they're tested to a life count that will statistically say, okay, that we can reliably obtain 10 lives from it. I believe the number -- when you get to these, you'll see that they were typically tested to 13 lives. And it's a set of instruments, you know, a set of, like, six instruments or something like that that's done for each one. So they're not tested to identify failure or failure mechanism. They're tested with the objective being to validate a specified 10-use life limit.

MR. VAN HOVEN: Page 2, the two paragraphs above Number 7.

BY MR. VAN HOVEN:

Q. And, Dr. Parnell, could you take a look at that and explain to the jury what that represents as to what you were just discussing as far as testing?

A. Yes. So the top paragraph here is describing things that would be identified as a failure. This is the failure criteria that is being applied. You know, if we saw a broken cable or a fractured component or a seized mechanism, those would be failures. And that would indicate, you know, a stopping at that point. You can't -- you can't continue the test of the device if that occurs.

But then in the second paragraph, it indicates the results here. All six of these instruments achieved 13 lives per the protocol. And these instruments passed all the life testing specs and requirements associated with that, with 13.

13 was so that, statistically, for the testing of six instruments, that you could say, with a high level of confidence and reliability, that, with this number of lives tested, that we can reliably confirm that a 10-life limit is acceptable.

Q. And if you wanted to see if a limit different than 10 was acceptable, or higher than 10, what would someone do?

A. You would test further. You would test for more number of lives in -- you might test until you identify some failures.

Here you're not -- not testing far enough to identify any failures under this protocol.

MR. VAN HOVEN: Pass the witness.

THE COURT: Thank you, Mr. Van Hoven.

MS. PARKER: Permission to approach the witness?

THE COURT: Granted.

(Counsel approaches witness.)

THE COURT: Proceed when ready, Ms. Parker.

CROSS-EXAMINATION

BY MS. PARKER:

Q. Good afternoon, Dr. Parnell.

A. Hello.

Q. My name is Crystal Parker. I'm an attorney for Intuitive, and I have a few questions for you.

Dr. Parnell, I'd actually like to start where your counsel left off, talking about Exhibit 572.

MS. PARKER: Mr. Lee, could we pull that up on the screen, please.

Q. Dr. Parnell, you were just discussing this life testing document with your counsel. Do you recall that?

A. Yes.

Q. And the specific EndoWrist being tested in this document is the Mega SutureCut needle driver; correct?

A. Yes.

Q. And I believe you mentioned in your direct exam testimony that the testing that was being conducted here was being conducted from September to October of 2009. Do you see that?

A. Yes.

Q. And the Mega SutureCut needle driver was already on the market in September and October of 2009; correct?

A. I believe -- I believe that's true.

Q. So the testing that was being conducted here wasn't the initial life testing to set the life of the instrument, was it?

A. If that's the case, if it was already out -- I mean, typically, this type of testing is done to provide that type of validation on life. This may be where they're coming back for additional testing or maybe the testing is just being done at

this point.

Q. So you're not sure what the purpose of this particular life testing was; correct?

A. Well, the timing relative to -- to the components beyond the market. I mean, if it wasn't tested before this, then the limits really are just set, just provided.

Q. Sir, I want you to concentrate on the question I'm asking.

Do you understand, sitting here today, why this life testing was being conducted in 2009?

A. According to this, that there was a test article that was specified and it says that the life testing was to be performed prior to the release of this instrument to the APL, to the approved products list.

Q. But -- I'm sorry. And what they were doing was testing a modification that they had made to an instrument that was already on the market; correct?

A. Yeah. It's not clear from this if there were -- if these were modifications, but it does indicate the time period and particular part numbers and such.

Q. Okay. And the specific purpose of this testing wasn't something that you took into consideration when reaching your opinions in this case, was it?

A. I'm sorry. Could you repeat that?

Q. Sitting here today, sir, you haven't been able to specifically identify for me what the purpose of this testing

was; correct?
A. Just what I read here, that the life testing was to be performed prior to the release of this instrument to the Approved Products List and this was completing that requirement for this particular instrument.
Q. Okay. But you don't know, sitting here today, whether or not this instrument was actually previously on the market, do you?
A. From this document, no, I don't know that.
Q. Okay. Thank you, sir.
Dr. Parnell, you talked a lot in your testimony about the Rebotix process of resetting the lives on EndoWrists; correct?
A. Yes.
Q. And just to make sure we're in agreement, what would trigger a hospital to send an EndoWrist to Rebotix to be reset would be that it would have one life left on the device; correct?
A. Yes, have at least one left, that's right.
Q. And an EndoWrist that's down to one remaining life, absent some other problem, is still functioning; correct?
A. That's right. It could be, or it could be that some issue has been identified at that point, but at least it has gotten to that number of lives successfully.
Q. And if an EndoWrist arrived at Rebotix's facility and was actually broken, Rebotix said it was unsuitable for repair;

right? You told us about that on your direct?
A. Yes, that's right. If it goes through the initial inspection procedure, and if there's issues that would make it unsuitable for repair, that could happen, yes.
Q. And, in fact, it's your understanding that under the Rebotix repair process, only EndoWrists that exhibited no signs of cable breakage, damages, or wear were considered for repair; right?
A. Yes. Generally, that's true. They had to be in -- without damage that could be identified through the inspection.
Q. So if an EndoWrist had, for example, a broken cable, Rebotix didn't even try to repair it; right?
A. That's correct.
Q. And the focus on their repair was primarily on resetting the use counter; right?
A. Well, not just resetting the use counter, although that's one of the steps, but also carrying out other types of steps that might be needed, sharpening of scissors, for example, or cable adjustment if there is looseness of the cables.
Q. But we can agree, sir, as you've already testified, that if a device as actually broken, they didn't try to repair it; right?
A. That's right. If there was physical damage that's identified in the inspection, then it wouldn't be a candidate for repair, for the service process.

Q. Dr. Parnell, you've offered a number of opinions in this case regarding Rebotix's ability to reset the use counters on the Si EndoWrists; correct?

A. Yes.

Q. And to be clear, all of that documentation that you reviewed about the process that you observed at Rebotix's facility, that all related to the reset process for the older generation S/Si EndoWrists; correct?

A. Yes. The process that they had developed and the means for being able to set the usage counter was associated with the S/Si instrument class.

Q. And during your direct exam, you told the jury about all of the documentation that you looked at related to Rebotix's process; right?

A. Yes.

Q. And I believe you testified to this, but in connection with your work on this case, you were able to review documents that had been produced by Rebotix from its company files in this litigation; right?

A. Yes, that's correct.

Q. And you reviewed that documentation in order to reach your opinions in this case; correct?

A. That was part of the work that I did, was associated with the documentation and review of documentation.

Q. And you reviewed those documents so that you'd be able to

sit up here today and tell the jury that you believe that Rebotix's reset process was thorough and reliable; right? Those were the words from your slides?

A. Yes. But between both documentation, process steps, and information that I gathered in my inspection visit at Rebotix, that was the conclusion I reached.

Q. Okay. Just to be clear, sir, you're aware that in 2014, Rebotix applied for FDA clearance to market modified EndoWrists, right? Just a yes-or-no answer, please, sir.

A. I -- I have -- I have seen some information to that effect.

Q. And you understand that Rebotix -- or excuse me. You understand that the FDA did not grant Rebotix clearance at that time; correct?

A. I didn't really pursue the review of that material, but...

Q. That wasn't something you considered in your opinions?

A. It wasn't something that I went into in depth.

Q. And you understand, sir, that Rebotix actually withdrew its application to the FDA in 2015; right?

A. I believe that's true.

Q. And you understand that Rebotix lacked FDA clearance when plaintiff SIS was working with it in 2019; correct?

A. It was -- it was not done under -- under an FDA process, if that's what you mean.

Q. Sir, I just want to be a little careful, so thank you.

So, sir, we can agree that when SIS began reselling S and Si EndoWrists in 2019, it was not the one actually doing the resetting; right?

A. For SIS, was your question?

Q. Yes. Let me ask again.

We can agree that when SIS began reselling reset EndoWrists in 2019, it was not the one doing the resetting, was it?

A. That's right. I mean, basically there -- there was work done to develop a business relationship associated with doing this. But it was to utilize the Rebotix process.

Q. And Rebotix was the one actually doing the resetting work; correct?

A. At that time, I think that's true. There was discussion of SIS being able to utilize it, but it was Rebotix's process that was being utilized.

Q. And just to be clear, sir, you mentioned SIS being able to do it. SIS never actually set up its own reset process using the Rebotix method, did it?

A. That's correct.

Q. Now, sir, you talked on your direct exam about all of the documents you looked at related to the Rebotix process, and you'll agree with me that a complete set of Rebotix's repair procedures, those aren't contained in a single document, are they?

A. That's right. There is the whole series of procedure and process specifications.

Q. And details about individual steps in the repair procedures can be contained in a number of different underlying documents; right?

A. Yes, that's also correct. Some documents were -- reference others; some are more general documents.

Q. And that cross-referencing between documents that you just talked about, that's routine in this type of work; correct?

A. Yes, I would say that's typical.

Q. So, for example, one document may say "perform a cutting test" but to understand the details of that test, you'd need to go look in another document that it pointed you to; right?

A. Yes, that's correct.

Q. And, Dr. Parnell, as part of your work on this case, you submitted two expert reports; correct?

A. Yes, that's correct.

Q. And in those reports, you wrote down all of your opinions in the case; correct?

A. Yes.

Q. And you also identified the documents that you relied on to support your opinions; correct?

A. Yes. There is -- there is an appendix that lists documentation that was available that I utilized.

Q. And I believe you talked about this on your direct exam;

but in the course of preparing your reports in this case, you actually had conversations with Mr. Posdal from SIS; correct?

A. Yes, that's correct.

Q. And I believe you mentioned on direct exam Mr. Posdal told you about his history with the people who worked at Rebotix; correct?

A. Yes, that they had a business relationship in the past for other purposes.

Q. And you reviewed Mr. Posdal's deposition transcripts; correct?

A. Yes.

Q. And you also reviewed the deposition Mr. Johnson of SIS; correct?

A. Yes.

Q. And in talking to Mr. Posdal and in reviewing his and Mr. Johnson's depo transcripts, you reached the opinion that it was reasonable for SIS to rely on the work that Rebotix had done; correct?

A. Reasonable, yes, but, you know, it was a part of developing a business relationship for -- for this activity, you know, beyond activities that they had done prior to this.

Q. And specifically, sir, you opined that SIS properly relied on its trusted technology partner Rebotix regarding the EndoWrist repair process in part because of their prior relationships; correct?

A. Yes.

Q. And not only that, you actually argued that it would make no sense for Rebotix to provide SIS with the technical details of its testing procedures; right?

A. I felt like at that -- at that stage of their negotiation for -- for setting up this work, I -- I was not surprised that, you know, full documentation was not provided at that stage. This was kind of early in the process of setting up that type of relationship.

Q. And just to be clear, sir, when you're talking about that stage, that stage was when SIS was already selling EndoWrists that Rebotix had reset; right?

A. I believe that's true in terms of ones that Rebotix had serviced.

Q. Correct.

And you even argue that Rebotix would have withheld its technical information and testing from SIS because providing that kind of technical detail could result in the possible loss of valuable intellectual property rights by Rebotix; right?

A. Yes, that's correct.

Q. And you made those arguments because the only Rebotix document that you were aware of SIS reviewing in the case was the summary of quality and reliability measures that you showed the jury earlier; right?

A. Yes. Summary of quality/reliability measures and, I

think, kind of the general sort of flow chart process that we also looked at today.

Q. Okay. And nowhere in your reports did you identify anyplace that SIS, Mr. Posdal or Mr. Johnson, told you that they had reviewed a binder of technical documents from Rebotix; right? You never identified that?

A. That's correct.

Q. Okay. And that's because you relied on Mr. Posdal's sworn deposition testimony where he testified that SIS never had access to Rebotix's technical files; right?

A. Yeah, it was consistent with that statement.

Q. Sir, I want you to take a look --

MS. PARKER: And if we could put that on the screen, Mr. Lee, it's in evidence, 136R.

Q. And, sir, this is a document that I believe your counsel showed you earlier; but if you need a copy of it, it will be in the binder in front of you.

MS. PARKER: And if, Mr. Johnson, we can -- excuse me, Mr. Lee, sorry. Let me start this again.

Sir, Mr. Lee, if we could please go to, excuse me, page 12 of Exhibit 136R.

Q. Dr. Parnell, do you recognize this as the summary of quality and reliability measures that you understood SIS had access to in the case?

A. Yes, I do.

Q. And we can tell SIS had access to this document because if you look in the lower right-hand corner, there's a stamp that starts with SIS. Do you see that?

A. Yes, meaning a Bates number that was produced in this litigation, yes.

Q. And we also know SIS had access to this document because if we look at the upper left-hand corner, they actually replaced Rebotix's branding with their own branding; correct?

A. Yes, that's correct.

Q. And if we take a look at pages 18 and 19 of the document, please, what we see, in this one document that SIS had access to, is a listing -- and it says this above the box: "A listing of the standards that were considered and applied in the development process by Rebotix."

Do you see that?

A. Yes.

Q. And what's listed here and then on the next page, as Mr. Lee has put on your screen, is a table that lists the standards that Rebotix purported to apply; correct?

A. Yes, that's correct, based on Rebotix's process.

Q. But, what we don't see here, or anywhere else in this document, is information actually showing how those standards were applied, do we?

A. That's right. I mean, this is still something of a -- of a preliminary document.

Q. And you'd have to go beyond this preliminary document to understand what test protocols were used; correct?

A. Yeah -- yes, that's correct.

Q. And you would have to go beyond this preliminary document to understand what test results were obtained from any test that was conducted; right?

A. Yes, that's correct, because we -- you know, we talked about that, kind of the stage of their relationship, at this point, for the EndoWrist service procedure.

Q. Okay. And because, as you told us earlier, the complete set of Rebotix's repair procedures and documentation, that's not contained in a single document; right?

A. That's correct.

Q. And you've not shown the jury today any other documents produced from SIS's files showing that they had access to any of that detailed technical information from Rebotix, have you?

A. That's correct.

Q. And, in fact, it's your opinion that even though SIS was already selling devices being reset by Rebotix, it would have made no sense for Rebotix to share that information; correct?

A. Yes, that's correct. Because this is the stage this work was at in terms of developing this business relationship for this process.

Q. But just to be clear, sir, that business relationship was developed enough that SIS felt comfortable selling Rebotix's

products to hospitals for use on patients; right?
A. Yes, that's true.
Q. Now, we've talked a little bit about the history between SIS and Rebotix, and you've not seen any evidence in this case that Intuitive had a history of working with Rebotix, have you?
A. No, I have not.
Q. And you've also not seen any evidence in the case that Intuitive had a history of working with SIS, have you?
A. I don't believe so. I don't recall anything there.
Q. And you've not seen any evidence in the case that Intuitive had a history of working with anyone who was running those companies, have you?
A. I -- I don't recall anything of that type.
Q. So while it was your belief that SIS had a reasonable basis to trust the work that Rebotix had done, you haven't identified any reason that Intuitive would have this same reasonable basis to trust whatever it was Rebotix and SIS were doing, have you?
A. That's -- that's correct. I don't think there -- there was any of the detailed procedures that were developed by Rebotix that were being shared with Intuitive. I haven't seen anything to that effect.
Q. And you had access to confidential information produced by both SIS and Intuitive in this case; correct?
A. Yes.

Q. And you also had access to information produced by Rebotix in this case; right?

A. Yes.

Q. And that's how you were able to review their documents regarding their reset process; right?

A. Yes, that's correct.

Q. But as you just told us, you've not shown the jury any evidence that Rebotix went to Intuitive and offered to provide Intuitive information about their reset process, have you?

A. I don't recall seeing anything of that type.

Q. And, sir, you're aware that in 2019, when Intuitive actually reached out to Rebotix and asked them for information, Rebotix refused to provide it; correct? They just didn't respond?

A. I don't recall that, but . . .

Q. Sure. Sir, let's take a look in your binder. If you go to what's marked as 1441R. It's already in evidence.

MS. PARKER: Mr. Lee, can we please put that on the screen?

Q. Just let me know when you're there, Dr. Parnell.

A. One four --

Q. 1441. It has an R at the end of it?

A. Yeah.

Q. Great. Thank you, sir. If you look at the first page of Exhibit 1441R, you can seeing this is an April 16, 2019, letter

to David Mixner at Rebotix Repair, LLC. Do you see that, sir?

A. Yes.

Q. And the subject of that letter is tampering with and reprogramming da Vinci Surgical System's instruments. Do you see that?

A. Yes, that's the subject of the letter.

Q. And if we look if the lower right-hand corner of that first page of the letter, sir, you see there's a stamp that starts with the letters R-E-B-O-T-I-X. Do you see that?

A. Yes. So this is a Bates Number and indicating that this is a Rebotix document.

Q. And by that, you mean that it was produced out of Rebotix's files in the litigation; correct?

A. Yes.

Q. Great. And if we could look at the second paragraph of the letter, sir, Intuitive writes to Rebotix (as read):

> "It's come to our attention that Rebotix's repair LLC," parentheses, Rebotix, "either directly or indirectly, through its service centers, is engaging in the unauthorized manufacturing and marketing of a medical device."
>
> Do you see that, sir?

A. Yes.

Q. (As read):

> "We also have concerns that the devices

potentially being distributed are not being manufactured or remanufactured, as the case may be, under a recognized quality management system applicable to medical devices."

Do you see that?

A. Yes.

Q. And if we turn to the third page of the letter, there's a section titled Factual Background. This is page 3 of 1441.

Do you see that section, sir?

A. Yes.

Q. And if we look at the third sentence of that Factual Background Section, Intuitive wrote (as read):

"With respect to many of the EndoWrist instruments, Intuitive Surgical determined 10 surgical procedures is the maximum number of safe and effective clinical uses prior to disposal. Accordingly, Intuitive placed a memory device inside each instrument that keeps track of usage count and inhibits the instrument from functioning after 10 uses."

Do you see that?

A. Yes, so this is a statement written by Intuitive Surgical.

Q. Correct.

And you know, sir, that Intuitive Surgical obtained FDA clearance to market the da Vinci and EndoWrists with a limited

number of uses; right?

A. Yes, that's correct.

Q. And if we look back at the letter, Intuitive went on and wrote (as read):

"We recently became aware that you were offering Intuitive customers in the United States a service where your authorized service centers will inspect and recondition EndoWrist instruments to allow the EndoWrist instrument to be used beyond their preprogrammed cleared number of uses."

Do you see that, sir?

A. Yes.

MS. PARKER: And, Mr. Lee, if we could now go to page 5 of Exhibit 1441, please.

THE COURT: While Mr. Lee takes you there, I just want to note we're just a touch over 2:30.

MS. PARKER: I just -- may I have two more minutes? Thank you, Your Honor.

BY MS. PARKER:

Q. Dr. Parnell, if you look at page 5 of the letter, there's a paragraph that starts with "lastly." Do you see that?

A. Yes.

Q. And what Intuitive wrote to Rebotix in 2019 (as read):

"Lastly, and most critically, Rebotix's modification of EndoWrist instruments impacts the

intended use of the device, extends the verified and validated testing performed by Intuitive, and, therefore, raises serious questions about the safety and effectiveness of the clinical use of such modified instruments in surgical procedures."

Do you see that?

A. Yes.

Q. If you turn to the last page of the letter, sir, which is page 6 of 1441, what Intuitive asked Rebotix at the end of this here is (as read):

"If you-allege that you and your service centers possess clinical proof that your service process returns modified instruments to a production equivalent specification and/or that additional use does not affect the safety or performance of the instruments, please provide proof of the same no later than April 30, 2019."

Did you see that, sir?

A. Yes.

Q. So Intuitive wrote to Rebotix in the spring of 2019 and raised concerns about the safety of what Rebotix was doing; right? You saw that in the letter?

A. Yes.

Q. And Intuitive specifically asked Rebotix to give it proof that its resetting process didn't affect the safety and

performance of EndoWrists; right?

A. Yes.

Q. Intuitive was asking Rebotix for the same type of information that you've told the jury you were able to review; correct?

A. The type of information that I described as part of the documentation and procedures that were associated with the Rebotix service procedure.

Q. That's what Intuitive was asking Rebotix for, right, something to show if it thought its process was safe and effective?

A. Yes, along that line, certainly.

Q. And you've not seen any evidence in the case that Rebotix ever provided that information to Intuitive, have you?

A. No, I have not.

MS. PARKER: That's a good place for me to break, Your Honor. Thank you.

THE COURT: Great. So we're going to recess for the afternoon.

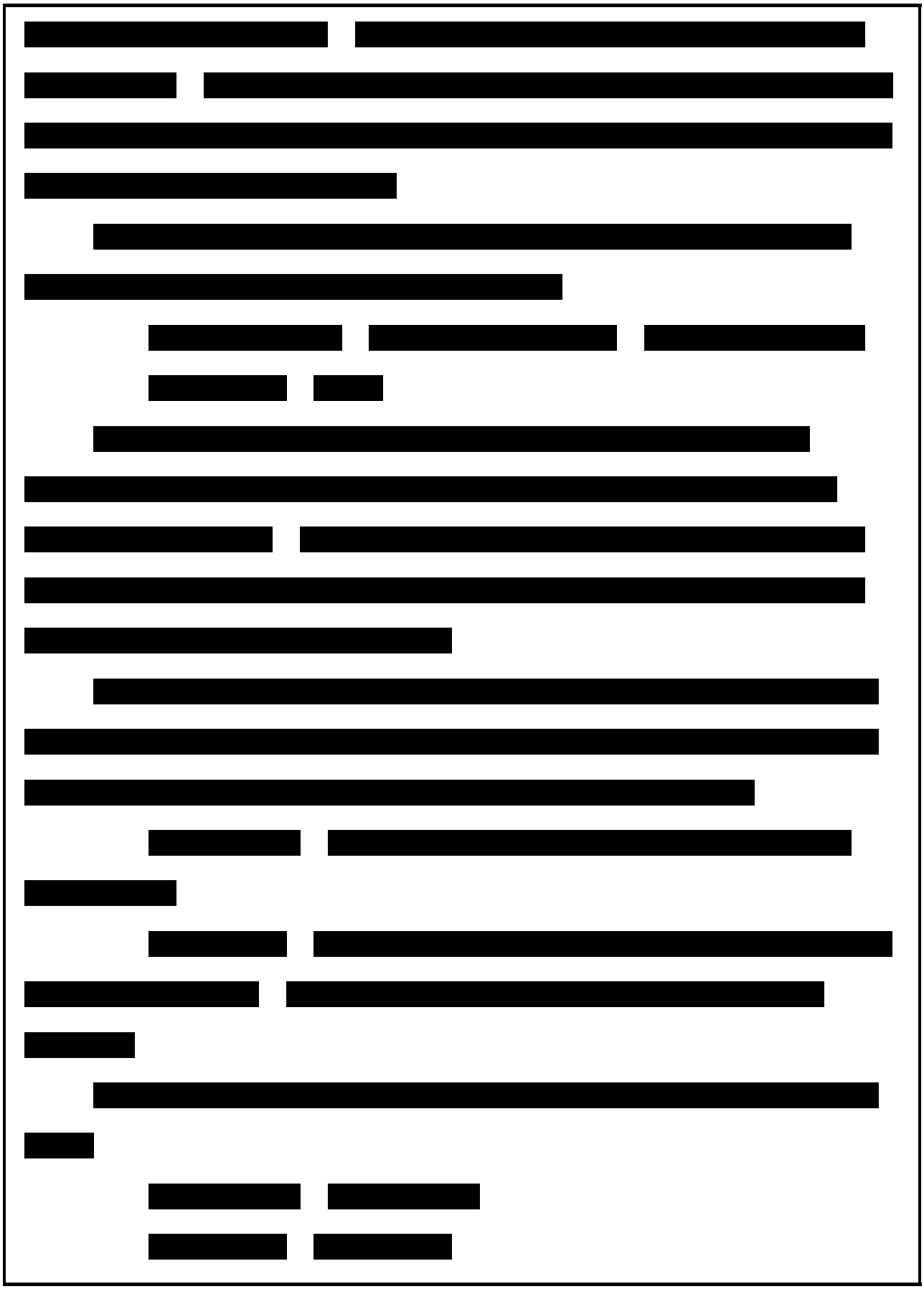
And thank our jury. I want to flag for you-all, for what it's worth, that we will be dark on Friday. I will remind you of this several times just as a -- just as you have four days this week. So congratulations on getting through day one of this week.

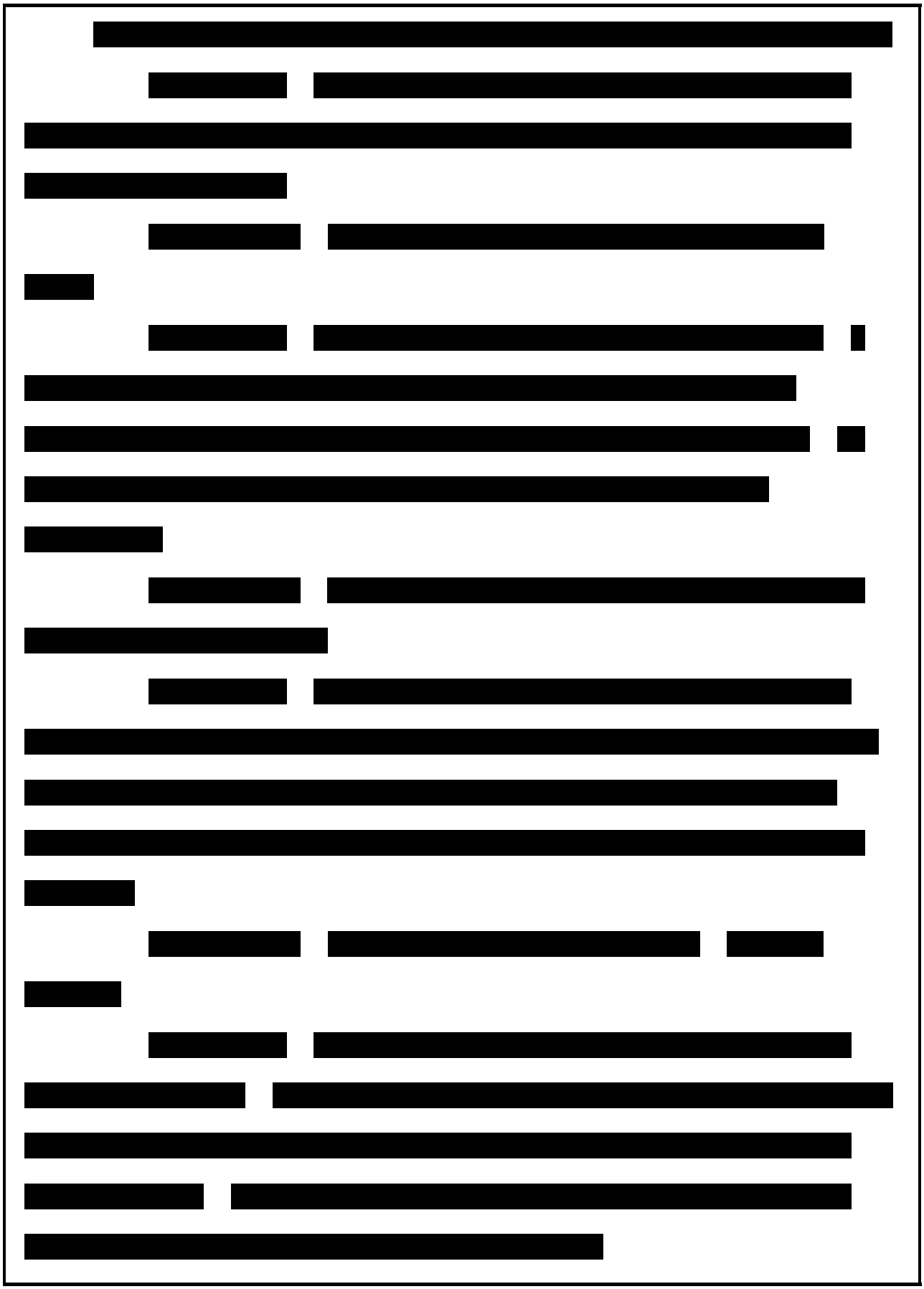
I remind you to please not discuss the case amongst

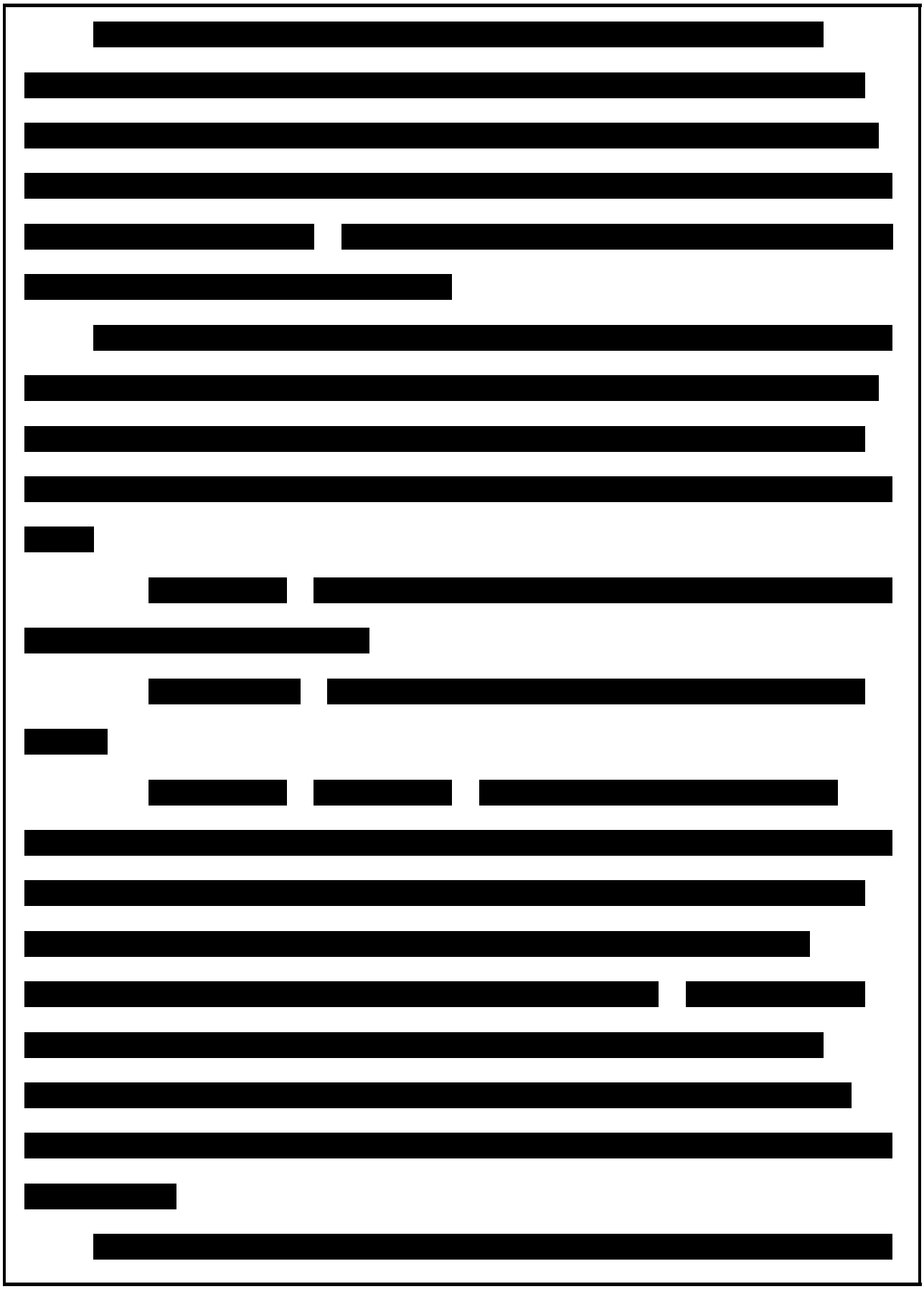
yourselves or with family members or loved ones in any way, electronic or otherwise, and not to do any research yourselves. We will see you-all tomorrow morning. Thank you.

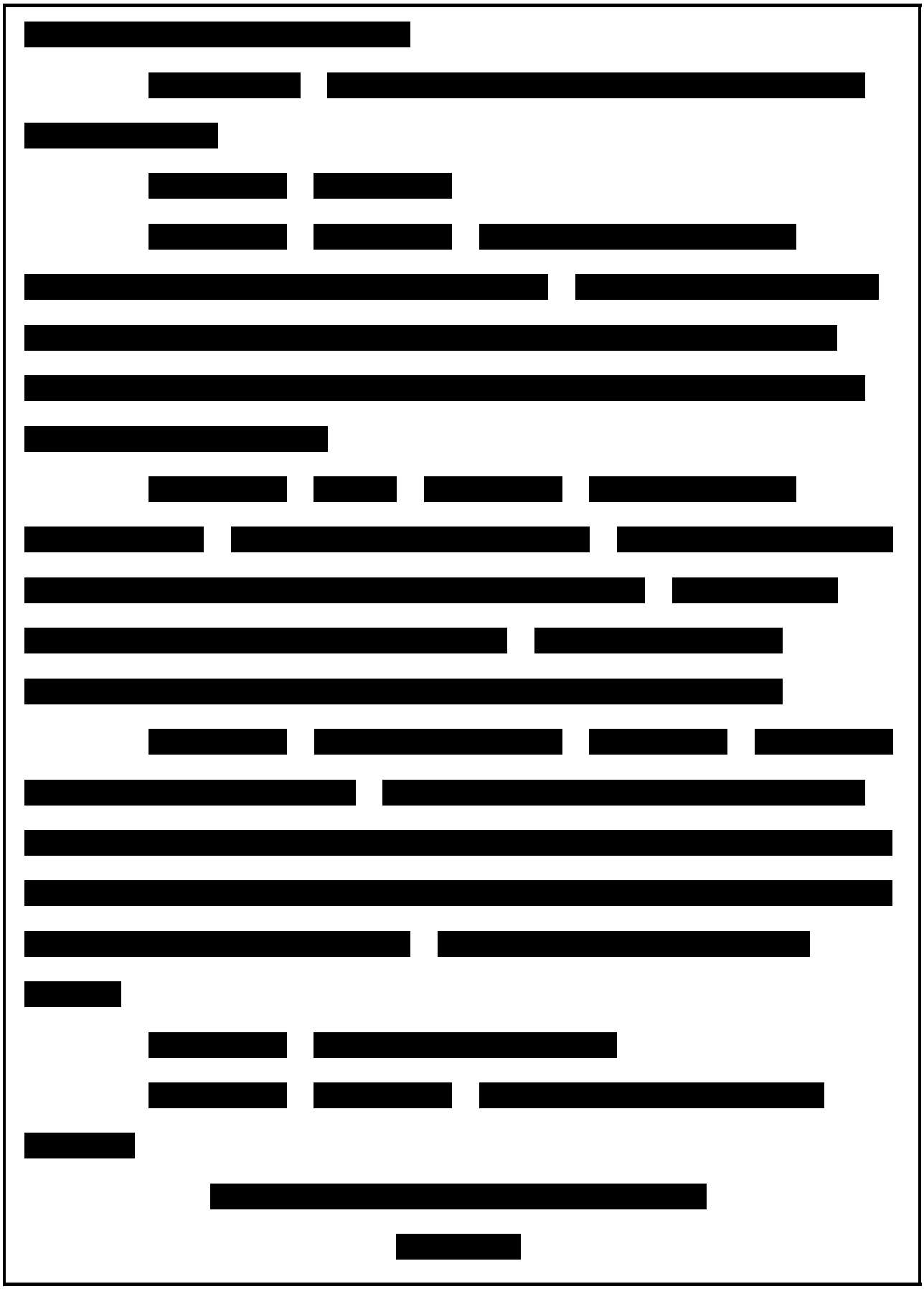
Please rise for the jury.

(The jury leaves the courtroom.)





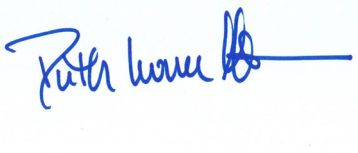




CERTIFICATE OF REPORTER

I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

DATE: Monday, January 13, 2025



Ruth Levine Ekhaus, RMR, RDR, FCRR, CCG, CSR No. 12219
Official Reporter, U.S. District Court

[redacted]

[redacted]

How long have you worked for SIS? 13:29:16

A Since 2008. 13:29:20

Q Have you held the same role for the entire 13:29:23
period you've worked for SIS? 13:29:26

A Yes. 13:29:31

Q So -- so that role, just to be clear, has 13:29:32
been executive VP of sales and clinical programs for 13:29:36
the full 14 month -- 14-year period? 13:29:37

A Correct. 13:29:41

[redacted]

DeSantis PA DC PR Merged

Designation List Report

DeSantis, Mr Bob **2021-05-27**

ID: V1M

V1M - DeSantis PA DC PR Merged

DESIGNATION	SOURCE	DURATION	ID
12:10 - 12:15	**DeSantis, Mr Bob 2021-05-27**	00:00:16	**V1M.1**
	12:10 Q. Could you please state your full name for the 12:11 record. 12:12 A. Yes. It's Robert James DeSantis. 12:13 Q. What is your position at Intuitive Surgical? 12:14 A. Executive vice president and chief product 12:15 officer.		
23:23 - 24:04	**DeSantis, Mr Bob 2021-05-27**	00:00:20	**V1M.2**
	23:23 Is it your understanding that Intuitive 23:24 designed the da Vinci robots to only function with 23:25 instruments that are produced by Intuitive? 24:01 A. Yes. 24:02 Q. And that was an intentional design decision; 24:03 right? 24:04 A. Absolutely.		
25:01 - 25:04	**DeSantis, Mr Bob 2021-05-27**	00:00:11	**V1M.3**
	25:01 Q. Are you aware of any other manufacturer in 25:02 the United States that sells EndoWrists that are 25:03 compatible with the da Vinci Surgical System? 25:04 A. No.		
25:05 - 25:09	**DeSantis, Mr Bob 2021-05-27**	00:00:15	**V1M.43**
	25:05 Q. Are you aware of any other manufacturers of 25:06 instruments or tools that can be attached to the 25:07 da Vinci Surgical System for use in minimally invasive 25:08 robotic surgery? 25:09 A. Yes.		
25:10 - 25:14	**DeSantis, Mr Bob 2021-05-27**	00:00:14	**V1M.66**
	25:10 Q. What system -- withdrawn. 25:11 What instruments? 25:12 A. So the question was instruments or 25:13 attachments? 25:14 Q. Let me -- let me rephrase.		
25:15 - 25:19	**DeSantis, Mr Bob 2021-05-27**	00:00:19	**V1M.4**
	25:15 Are you aware of any other manufacturer in 25:16 the United States that sells instruments that can be 25:17 attached to the da Vinci robot and used for minimally 25:18 invasive surgery? 25:19 A. No.		

V1M - DeSantis PA DC PR Merged

DESIGNATION	SOURCE	DURATION	ID
29:20 - 30:02	**DeSantis, Mr Bob 2021-05-27**	00:00:33	**V1M.5**
	29:20 Q. What did you mean when you said 'a true 29:21 robotic competitive threat'? 29:22 A. So my thought here was that robotics is 29:23 differentiated from lap and its value proposition. So 29:24 therefore, when we think about our place in the 29:25 market, we should be thinking about our robotic 30:01 offering versus other robotic offerings rather than 30:02 lap.		
32:25 - 33:10	**DeSantis, Mr Bob 2021-05-27**	00:00:36	**V1M.6**
	32:25 Q. Now, Stryker Sustain- -- withdrawn. 33:01 Has -- withdrawn. 33:02 Has Stryker Sustainability brought a robot to 33:03 the United States market? 33:04 A. Stryker has. 33:05 Q. What is that robot? 33:06 A. It's Mako surgical system. 33:07 Q. Is that an orthopedic robot? 33:08 A. It is. 33:09 Q. So that's not a soft tissue robot; right? 33:10 A. Not to my understanding. Correct.		
37:13 - 37:17	**DeSantis, Mr Bob 2021-05-27**	00:00:14	**V1M.44**
	37:13 This presentation has a date of August 16, 37:14 2020. 37:15 So at that date, are you aware of any other 37:16 surgical systems that were in the U.S. market with the 37:17 da Vinci robots listed here?		
37:23 - 38:02	**DeSantis, Mr Bob 2021-05-27**	00:00:13	**V1M.45**
	37:23 MR. ERWIG: Q: Which system? 37:24 A. There's a system from a company called 37:25 TransEnterix. 38:01 Q. Is that the TransEnterix Senhance? 38:02 A. It is.		
39:12 - 39:22	**DeSantis, Mr Bob 2021-05-27**	00:00:31	**V1M.7**
	39:12 Q. My question is just, is there any other 39:13 system other than the TransEnterix Senhance? 39:14 A. So I don't know what you're getting at with 39:15 the question. It's not specific. I'm certain there 39:16 are lots of systems. There are lots of orthopedic		

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DESIGNATION	SOURCE	DURATION	ID
	39:17 systems. There are lots of different types of 39:18 endoluminal, cardiac, et cetera, systems that are in 39:19 the market in the U.S. 39:20 Q. Now, those systems, those aren't soft tissue 39:21 surgical robots; right? 39:22 A. Correct.		
56:19 - 56:22	**DeSantis, Mr Bob 2021-05-27**	00:00:21	**V1M.8**
	56:19 Q. Has there been compelling competition such 56:20 that surgeons have switched away from the da Vinci 56:21 robot to some other system? 56:22 A. To date, little.		
58:09 - 58:17	**DeSantis, Mr Bob 2021-05-27**	00:00:23	**V1M.9**
	58:09 Q. One barrier to entry might be that there's a 58:10 lot of investment and a lot of time that's required to 58:11 bring a product to market; right? 58:12 A. Yes. 58:13 Q. Is it your understanding that it takes a lot 58:14 of time and a large investment to bring a soft tissue 58:15 surgical robot to market? 58:16 A. It does take a lot of time and investment to 58:17 bring a soft tissue robot to market, yes.		
58:25 - 59:13	**DeSantis, Mr Bob 2021-05-27**	00:00:44	**V1M.46**
	58:25 Q. You say 'indirectly.' What do you mean by 59:01 that? 59:02 A. The company -- I'll kind of go back to what I 59:03 said earlier. You know, the company believes in 59:04 putting patients first, providing technologies to 59:05 surgeons that will help them help patients. So that's 59:06 been our strategy, and that's been our mission. 59:07 In doing that, you know, we've spent a lot of 59:08 time and money and -- and effort and -- and developed 59:09 the soft tissue robot. 59:10 The fact that that is a barrier for others, 59:11 et cetera, is a -- kind of a side effect of what -- 59:12 what our -- our effort has been and what our mission 59:13 has been.		
59:14 - 59:21	**DeSantis, Mr Bob 2021-05-27**	00:00:30	**V1M.10**
	59:14 Q. There's some challenges that potential 59:15 competitors face when they're trying to -- to break		

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DESIGNATION	SOURCE	DURATION	ID
	59:16 into that market of providing care to patients; right? 59:17 A. Yes. 59:18 Q. One challenge is that there is an already 59:19 large install base of da Vinci robots in hospitals 59:20 around the United States; is that right? 59:21 A. Yes.		
59:22 - 60:14	**DeSantis, Mr Bob 2021-05-27**	00:01:07	**V1M.67**
	59:22 Q. Another challenge is that surgeons have had a 59:23 great deal of training on the da Vinci Surgical 59:24 System; right? 59:25 A. So we talked about in terms like a great deal 60:01 of training earlier. And I would agree that their 60:02 experience on the platform is an advantage to them and 60:03 something that a competitor would have to address. 60:04 Q. There's also some intellectual property 60:05 protections that Intuitive has that might be a 60:06 challenge for another company to design around; right? 60:07 A. Yes. 60:08 Q. And another challenge for entry might be that 60:09 the EndoWrists, they only work with a -- withdrawn. 60:10 Another challenge might be that the da Vinci 60:11 robot only works with Intuitive manufactured 60:12 instruments; right? 60:13 A. Other than the instruments in question in 60:14 this case, yes.		
63:25 - 64:05	**DeSantis, Mr Bob 2021-05-27**	00:00:16	**V1M.47**
	63:25 Q. Well, how about today? Is it your 64:01 understanding that it will take multiple years for a 64:02 legitimate competitive threat to Intuitive to 64:03 materialize? 64:04 A. I believe we have legitimate competitive 64:05 threats today.		
69:19 - 69:24	**DeSantis, Mr Bob 2021-05-27**	00:00:20	**V1M.11**
	69:19 MR. ERWIG: Q: Now, in the period between 69:20 1999 and 2019, were there any viable alternatives to a 69:21 surgeon that wanted to perform a minimally invasive 69:22 soft tissue robotic surgery other than the da Vinci 69:23 surgical robot? 69:24 A. No, I don't believe so.		

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DESIGNATION	SOURCE	DURATION	ID
78:17 - 78:20	**DeSantis, Mr Bob 2021-05-27**	00:00:11	**V1M.12**
	78:17 Q. Is it your understanding that robots that 78:18 don't perform any of the same procedures as the 78:19 da Vinci robot are in direct competition with the 78:20 da Vinci soft tissue surgical robot?		
78:21 - 78:24	**DeSantis, Mr Bob 2021-05-27**	00:00:10	**V1M.13**
	78:21 A. Today, if they're not performing the same 78:22 procedures that we are performing, I think that's a 78:23 fair statement. Then we're not in competition, by 78:24 definition.		
107:14 - 107:25	**DeSantis, Mr Bob 2021-05-27**	00:00:43	**V1M.14**
	107:14 Intuitive markets robotic instruments as 107:15 having some advantages over traditional laparoscopic 107:16 surgery; right? 107:17 A. The -- the overall surgical platform has 107:18 advantages over laparoscopic instruments, yes. 107:19 Q. When you mentioned 'the overall surgical 107:20 platform,' that includes the actual robot that's 107:21 performing surgery on the patient; right? 107:22 A. Yes. 107:23 Q. Includes the surgeon console at which the 107:24 surgeon sits during the procedure; right? 107:25 A. Yes.		
108:03 - 108:07	**DeSantis, Mr Bob 2021-05-27**	00:00:15	**V1M.15**
	108:03 One of the advantages that Intuitive markets 108:04 is that robotic surgeries allow the surgeon a greater 108:05 range of motion than a surgeon would have with a human 108:06 hand; right? 108:07 A. Yes.		
108:13 - 109:06	**DeSantis, Mr Bob 2021-05-27**	00:01:01	**V1M.16**
	108:13 The -- the surgeon can -- can calibrate the 108:14 joystick so that larger movements on the joystick will 108:15 translate to smaller movements of the -- of the 108:16 EndoWrist; right? 108:17 A. Yes. 108:18 Q. And that's an advantage that Intuitive 108:19 markets of robotic surgery relative to laparoscopic 108:20 surgery; right? 108:21 A. Yes.		

DESIGNATION	SOURCE	DURATION	ID
	108:22 Q. Another advantage that Intuitive markets is 108:23 that the surgeon can stay seated during the entire 108:24 procedure; right? 108:25 A. I'm struggling with the specifics of the 109:01 question. If -- my -- my words would be greater 109:02 precision, control, ergonomics are all benefits 109:03 associated with the da Vinci platform. 109:04 Q. And those are all benefits that Intuitive 109:05 markets that the da Vinci platform has over 109:06 traditional laparoscopic surgery; right?		
109:07 - 110:23	**DeSantis, Mr Bob 2021-05-27**	00:02:11	**V1M.17**
	109:07 A. Yes. 109:08 Q. Now, the actual manner in which the surgery 109:09 is performed, I want to get an understanding from you 109:10 about that a little bit. 109:11 So in a -- in a traditional laparoscopic 109:12 surgery, the surgeon would be standing next to the 109:13 patient; right? 109:14 A. Yes. 109:15 Q. The surgeon might have some assistants there 109:16 with him as well; right? 109:17 A. Yes. 109:18 Q. And the surgeon would make a number of small 109:19 incisions; right? 109:20 A. Yes. 109:21 Q. And typically, about what -- what size are 109:22 those incisions? 109:23 A. If it's laparoscopic surgery and for 109:24 laparoscopic access, it's anywhere from 109:25 2.3 millimeters up to 15-plus millimeters. 110:01 Q. And for those of us that can't conceptualize 110:02 millimeters, do you have some sort of a -- sort of an 110:03 object that might be a useful metric for that, like 110:04 the size of a penny? Size of a fingernail? 110:05 A. Size of a penny is about 12 millimeters. 110:06 Hopefully, there are no engineers here because I might 110:07 be wrong. But the -- the size of a pencil is about 110:08 6 to 7 millimeters. 110:09 Q. When you says 'the size of a pencil,' do you 110:10 mean the -- the end of the pencil, right, not the		

DESIGNATION	SOURCE	DURATION	ID
	110:11 length of the pencil? 110:12 A. The diameter, yeah. 110:13 Q. So you might have an incision that's a little 110:14 larger than a -- than a penny around; right? 110:15 A. Yes, in that range. 110:16 Q. You could also have a smaller incision than 110:17 that; right? 110:18 A. Yes. It can be smaller. It can be larger. 110:19 Q. And down to a -- a couple of millimeters. 110:20 That would be about the size of the end of the -- 110:21 withdrawn. 110:22 A. couple of millimeters, that might be around 110:23 the size of the tip of a pencil; right?		
110:24 - 111:20	**DeSantis, Mr Bob 2021-05-27** 110:24 A The tip of a pencil column usually at varying 110:25 diameters. I'm trying to think of a general 111:01 reference. 111:02 The power cable on most laptops is about 2 to 111:03 3 millimeters. 111:04 Q. So somewhere between the size of a power 111:05 cable on a laptop or the size of a penny, that would 111:06 be a rough range of the size of incisions made in 111:07 minimally invasive surgery; right? 111:08 A. So I -- the range would be -- sorry for the 111:09 bad analogy, the reference, but the size of a power 111:10 cable all the way up to the size of almost a quarter, 111:11 I would say, is the range. Okay. 111:12 Q. So the largest type of incision, that would 111:13 be around the -- is that the quarter -- going straight 111:14 across the quarter, that's about the size of an 111:15 incision that's at the higher range for a minimally 111:16 invasive surgery? 111:17 A. Yes. 111:18 Q. Now, for open surgery, about how long are 111:19 those incisions? 111:20 A. It really depends on the surgical procedure.	00:01:11	**V1M.18**
112:21 - 112:23	**DeSantis, Mr Bob 2021-05-27** 112:21 Q. Sure. My question is, there is a -- there is 112:22 a range of the length of incisions that can be 112:23 performed in -- in open surgeries; right?	00:00:09	**V1M.19**

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DESIGNATION	SOURCE	DURATION	ID
112:24 - 114:01	**DeSantis, Mr Bob 2021-05-27**	00:01:29	**V1M.20**
	112:24 A. Yes. 112:25 Q. Those can be very small or -- well, 113:01 withdrawn. 113:02 Those can be on the -- on the smaller end, 113:03 depending on the procedure; right? 113:04 A. Yes. 113:05 Q. And they can be on the -- on the much larger 113:06 end as well, depending on the procedure; right? 113:07 A. Yes. 113:08 Q. Now, in the smaller end for those procedures, 113:09 about how large would the incision be for a -- an open 113:10 surgery? 113:11 A. The smallest I've seen was two weeks ago. My 113:12 daughter had an open epigastric hernia procedure that 113:13 was about the size of a penny, the incision. 113:14 Q. How about the largest that you've seen? 113:15 A. Surgery in general, I've seen procedures that 113:16 span the human body. 113:17 Q. Do you have a sense of the normal range of -- 113:18 well, withdrawn. 113:19 One of the things that we talked about with 113:20 traditional instruments as being a challenge is that 113:21 they require larger incisions for access; right? 113:22 A. Yes. 113:23 Q. So for a laparoscopic procedure, for example, 113:24 one of the advantages is that you're able to make a 113:25 much smaller incision to have access; right? 114:01 A. Yes.		
130:10 - 130:13	**DeSantis, Mr Bob 2021-05-27**	00:00:10	**V1M.48**
	130:10 Q. And so Intuitive through software sets the 130:11 number of uses for a surgical EndoWrist in the 130:12 housing; right? 130:13 A. Yes.		
130:15 - 130:18	**DeSantis, Mr Bob 2021-05-27**	00:00:13	**V1M.49**
	130:15 And typically, 8 mm instruments, they have 130:16 about ten uses; right? 130:17 A. The Si instruments, typical 8 mm have ten 130:18 uses, yes.		
130:19 - 131:06	**DeSantis, Mr Bob 2021-05-27**	00:00:29	**V1M.21**

DESIGNATION	SOURCE	DURATION	ID
	130:19 Q. When those ten uses are up, the 130:20 instrument will no longer function with a da Vinci 130:21 robot; right? 130:22 A. Correct. 130:23 Q. What that means is if a surgeon tries to 130:24 initiate a surgery using an instrument that doesn't 130:25 have any uses remaining, then the da Vinci will flash 131:01 an error message; right? 131:02 A. Correct. If they try to use an expired 131:03 instrument, they will be informed that it's an expired 131:04 instrument -- 131:05 Q. And the -- 131:06 A. -- and it will not work.		V1M.21
134:21 - 135:08	**DeSantis, Mr Bob 2021-05-27** 134:21 Q. Those traditional laparoscopic instruments, 134:22 they can -- they can fail at times; right? 134:23 A. Yes. 134:24 Q. The scissors, for example, they might not be 134:25 sharp enough to cut tissue anymore; right? 135:01 A. That's one failure mode, yes. 135:02 Q. The graspers, they might become misaligned 135:03 or, you know, they might not be able to -- to grasp 135:04 effectively anymore; right? 135:05 A. Yes. 135:06 Q. And the needle driver, that might not be able 135:07 to hold the needle in place tightly anymore; right? 135:08 A. Yes.	00:00:33	V1M.22
137:20 - 138:06	**DeSantis, Mr Bob 2021-05-27** 137:20 Q. Is there a difference in terms of how long 137:21 traditional laparoscopic instruments are used as 137:22 compared to Intuitive's EndoWrists? 137:23 A. Within a procedure, or the number of 137:24 procedures? 137:25 Q. Number of procedures. 138:01 A. You know, so our Si instruments generally are 138:02 indicated for ten lives. I don't have data on how 138:03 many lives reusable laparoscopic hand instruments last 138:04 and specifics about the different types and 138:05 reprocessing, remanufacturing of laparoscopic 138:06 instruments.	00:00:44	V1M.23

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DESIGNATION	SOURCE	DURATION	ID
139:24 - 140:05	**DeSantis, Mr Bob 2021-05-27**	00:00:15	**V1M.24**
	139:24 Traditional laparoscopic instruments can't be 139:25 attached to the arms of the da Vinci surgical robot; 140:01 is that right? 140:02 A. That's correct. 140:03 Q. And instruments designed for other surgical 140:04 robots, those also can't be attached to the da Vinci 140:05 surgical robot; true?		
140:09 - 140:09	**DeSantis, Mr Bob 2021-05-27**	00:00:02	**V1M.25**
	140:09 THE WITNESS: It's still correct.		
143:21 - 143:23	**DeSantis, Mr Bob 2021-05-27**	00:00:10	**V1M.50**
	143:21 Q. Now, EndoWrists can fail before their 143:22 indicated number of uses; right? 143:23 A. Yes.		
144:06 - 144:09	**DeSantis, Mr Bob 2021-05-27**	00:00:10	**V1M.51**
	144:06 Q. Now, when hospitals report those failures, 144:07 it's my understanding that Intuitive oftentimes takes 144:08 the instrument back from hospitals; right? 144:09 A. Yes.		
144:10 - 144:14	**DeSantis, Mr Bob 2021-05-27**	00:00:20	**V1M.26**
	144:10 Q. After Intuitive has taken that instrument 144:11 back from hospitals, does Intuitive attempt to 144:12 refurbish that instrument to return it to new working 144:13 order? 144:14 A. No, that's not our current process.		
144:15 - 144:20	**DeSantis, Mr Bob 2021-05-27**	00:00:22	**V1M.52**
	144:15 Q. Instead, what Intuitive does is it looks at 144:16 what the potential failure was caused by; right? 144:17 A. Yes. We try to understand why it failed 144:18 previous to its indicated lives. And we will feed 144:19 that back to our engineering manufacturing quality 144:20 teams to try and improve.		
144:25 - 145:25	**DeSantis, Mr Bob 2021-05-27**	00:01:18	**V1M.68**
	144:25 Q. And EndoWrists might have unintuitive motion, 145:01 for example? 145:02 A. That's one failure mode, yes. 145:03 Q. That might happen even before the use counter 145:04 has ever expired; right?		

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DESIGNATION	SOURCE	DURATION	ID
	145:05 A. It might, yes. 145:06 Q. And it could happen even -- even during a 145:07 surgery; right? 145:08 A. Yes. 145:09 Q. Another issue that might happen is that the 145:10 EndoWrist might not have sufficient grasping force; 145:11 right? 145:12 A. Correct. 145:13 Q. And that might happen before the lives on the 145:14 use counter have run out; true? 145:15 A. It -- it's possible, yes. So this is -- this 145:16 is the reason we do live testing. We do live testing 145:17 to be able to say things like that will not happen 145:18 95 percent of the time with 95 percent confidence. 145:19 And depending on the failure mode, grasping 145:20 versus cutting versus stapling versus -- we will set 145:21 higher and higher specification confidence levels. 145:22 And if we have a lot of things come back from 145:23 the field like you're talking about that are not 145:24 satisfying our requirements, we are required to do 145:25 something about that.		
146:01 - 146:02	**DeSantis, Mr Bob 2021-05-27** 146:01 Q. Has Intuitive performed any -- any testing on 146:02 instruments that -- well, withdrawn.	00:00:06	**V1M.69**
146:03 - 146:15	**DeSantis, Mr Bob 2021-05-27** 146:03 Let's take one kind of specific example, an 146:04 EndoWrist that has unintuitive motion; okay? 146:05 Are you with me? 146:06 A. Yes. 146:07 Q. The hospital might report that to Intuitive 146:08 and send the EndoWrist back; right? 146:09 A. Yes. 146:10 Q. When Intuitive receives that instrument, does 146:11 Intuitive try to examine whether that unintuitive 146:12 motion can be repaired? 146:13 A. No, that's not the primary investigation. 146:14 We're not looking to repair the instruments that are 146:15 coming back.	00:00:38	**V1M.27**
146:16 - 146:25	**DeSantis, Mr Bob 2021-05-27** 146:16 Q. Well, is that -- is that any part of the	00:00:42	**V1M.70**

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DESIGNATION	SOURCE	DURATION	ID
	146:17 investigation, looking at, Hey, you know, could we -- 146:18 could we repair this and fix that issue? 146:19 A. Not normally, no. 146:20 Q. Does Intuitive have any interest in 146:21 performing those types of tests when an instrument 146:22 comes back from a -- from a hospital? 146:23 A. We have certainly done evaluations on being 146:24 able to harvest instruments and be able to 146:25 remanufacture them, yes.		
171:01 - 171:08	**DeSantis, Mr Bob 2021-05-27**	00:00:26	**V1M.53**
	171:01 Q. And over the years there were some -- some 171:02 changes to the da Vinci Si instruments; right? 171:03 A. Yes. 171:04 Q. And so if you had, at every point, wanted to 171:05 give the maximum amount of uses to the customer, you 171:06 would have tested those at various points and seen 171:07 what the appropriate use limits were; right? 171:08 A. Not necessarily, no.		
171:11 - 171:13	**DeSantis, Mr Bob 2021-05-27**	00:00:08	**V1M.71**
	171:11 The Si instruments, they were typically 171:12 initially set at ten lives; right? 171:13 A. Yes.		
171:15 - 171:22	**DeSantis, Mr Bob 2021-05-27**	00:00:23	**V1M.72**
	171:15 Now, there were some changes and updates to 171:16 various types of instruments over the years; right? 171:17 A. Yes. 171:18 Q. And, for example, in 2012, you could have 171:19 tested the instruments and seen, Hey, are we seeing a 171:20 higher number of uses that we can get out of them, 171:21 right, using our life testing? 171:22 A. We could have, yes.		
171:23 - 172:14	**DeSantis, Mr Bob 2021-05-27**	00:00:59	**V1M.54**
	171:23 Q. And if the instruments had gotten better, 171:24 that might have shown these can now use -- or your 171:25 testing method be used for 13 or 14 lives; right? 172:01 A. Yeah, I want to refer back to what I said 172:02 earlier is that it's not just lives. That there's 172:03 other variables in play, like customer satisfaction, 172:04 quality level, RMA levels, et cetera.		

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	172:05 So as you make improvements or you make 172:06 changes, the changes may have been reactive to quality 172:07 problems. They may have been improvements to try and 172:08 improve a, you know, the durability, reliability. You 172:09 can either -- you know, that may be intended to drive 172:10 the quality and customer satisfaction at the currently 172:11 indicated lives higher. 172:12 You know, so it's not just making 172:13 improvement. It's -- it's more lives on the 172:14 instrument.		
172:15 - 173:01	**DeSantis, Mr Bob 2021-05-27**	00:00:44	**V1M.73**
	172:15 Q. Well, you could certainly have tested the Si 172:16 instruments in 2013 to determine whether additional 172:17 lives were warranted; right? 172:18 A. We could have, yes. 172:19 Q. Did Intuitive, in fact, do any such testing? 172:20 A. I don't know. 172:21 Q. Are you aware of any? 172:22 A. Not off the top of my head. 172:23 We also changed, because of an audit finding, 172:24 our statistical-based method and the rigor behind it 172:25 which made things harder in 2014. But anyway the 173:01 answer is not that I'm aware.		
173:02 - 173:17	**DeSantis, Mr Bob 2021-05-27**	00:00:59	**V1M.28**
	173:02 Q. Now, in 2013, if Intuitive wanted to give 173:03 hospitals the maximum possible number of uses out of 173:04 every Si instrument, Intuitive could have tested the 173:05 Si instruments and seen what the appropriate number of 173:06 uses was as of that time; right? 173:07 A. That's -- that's one option, yes. 173:08 Q. Instead Intuitive left the life counter for 173:09 the Si instruments at ten uses; right? 173:10 A. Intuitive was investing heavily in a better 173:11 platform at that time, so we did not choose to invest 173:12 in the Si instruments to do a life testing and roll 173:13 out that program. Correct, we did not do that. 173:14 Q. And so Intuitive left the life counter of the 173:15 Si instruments at ten uses and didn't try to increase 173:16 it to 12, 13, or anything else; right? 173:17 A. Correct.		

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177:18 - 178:07	**DeSantis, Mr Bob 2021-05-27**	00:01:04	**V1M.55**
	177:18 Q. As of this time period, could you have tested 177:19 the Monopolar instruments to increase the number of 177:20 lives on those instruments as well? 177:21 A. We could have. We did not. 177:22 Q. Why not? 177:23 A. You know, I mentioned earlier that patient 177:24 safety, product requirements, our risk analyses go 177:25 into our specifications, one of which is the number of 178:01 indicated lives. 178:02 the Monopolar instrument is our highest risk 178:03 instrument. The failure modes are the most severe. 178:04 They are a scissor. They are the high -- highest 178:05 complaint rate. So there was just -- the risk reward 178:06 associated with raising the Monopolar instrument lives 178:07 was -- was not there. Did not make sense.		
202:07 - 202:08	**DeSantis, Mr Bob 2021-05-27**	00:00:06	**V1M.29**
	202:07 About how many RMA EndoWrists does Intuitive 202:08 receive back from hospitals each year?		
202:09 - 202:21	**DeSantis, Mr Bob 2021-05-27**	00:00:53	**V1M.30**
	202:09 A. R -- RMA per procedure is about 2 percent, a 202:10 little higher. There are typically three to four 202:11 instruments used per procedure. We did about 202:12 1.5 million procedures. So 2 percent of 1.5 million 202:13 would be the way I would estimate it right now which 202:14 is about 30,000. 202:15 Q. So about 30,000 instruments were RMAed to 202:16 Intuitive, and is that in 2020? 2019? 202:17 A. It -- either one. It would be close to the 202:18 year 2019, yes. 202:19 Q. So taking 2019, there may be around 30,000 202:20 instruments that were RMAed to Intuitive; right? 202:21 A. Yeah, let me check my math.		
202:22 - 202:22	**DeSantis, Mr Bob 2021-05-27**	00:00:03	**V1M.31**
	202:22 It's a reasonable estimate.		
210:15 - 211:01	**DeSantis, Mr Bob 2021-05-27**	00:00:46	**V1M.32**
	210:15 Intuitive has never taken an instrument 210:16 refurbished by Rebotix and examined whether it 210:17 effectively operates with a da Vinci surgical system;		

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	210:18 right?		
	210:19 A. Well, we've had a few come back to us. And		
	210:20 in our complaints and RMAs, and just like all others,		
	210:21 we take and evaluate whether they're working properly.		
	210:22 Q. Intuitive hasn't, for example, taken an		
	210:23 instrument that's in use by the hospital that's an		
	210:24 instrument that's been refurbished by Rebotix and		
	210:25 performs testing to determine whether that instrument		
	211:01 operates appropriately during surgery; right?		
211:12 - 212:01	**DeSantis, Mr Bob 2021-05-27**	00:00:55	**V1M.33**
	211:12 THE WITNESS: So we have not done V&V or life		
	211:13 testing on third-party remanufactured instruments, no.		
	211:14 MR. ERWIG: Q: There's been no testing, in		
	211:15 fact, of any kind done by Intuitive to determine the		
	211:16 efficacy of -- withdrawn.		
	211:17 There's been no testing of any kind by		
	211:18 Intuitive to determine the safety of instruments that		
	211:19 have been modified by Rebotix Repair; right?		
	211:20 A. Well, we -- we can extrapolate, based on our		
	211:21 own testing of our instruments which they are		
	211:22 modifying and extending beyond their indicated life.		
	211:23 There are, you know, millions of procedures		
	211:24 with those instruments and their quality level,		
	211:25 et cetera. But have we -- have we done their V&V		
	212:01 testing? No, we have not.		
213:18 - 217:07	**DeSantis, Mr Bob 2021-05-27**	00:04:32	**V1M.34**
	213:18 One of the types of EndoWrists is an		
	213:19 EndoWrist that has a pair of scissors on the end;		
	213:20 right?		
	213:21 A. Yes.		
	213:22 Q. One of the failure conditions for that		
	213:23 EndoWrist can be that the scissors become too dull to		
	213:24 cut tissue; right?		
	213:25 A. Yes.		
	214:01 Q. And when the scissors do, in fact, become too		
	214:02 dull, Intuitive classifies that as a failure of the		
	214:03 EndoWrist; right?		
	214:04 A. Yes. If a customer files a complaint and		
	214:05 says it's not cutting, we test it to see if it's		
	214:06 cutting to our specs. If it's not, we classify that		

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214:07 as a failure.
214:08 Q. Well, even before an Intuitive life
214:09 testing -- dull scissors would constitute a failure of
214:10 the instrument; right?
214:11 A. I don't understand the question.
214:12 Q. Well, Intuitive initially does some -- some
214:13 life testing. We discussed that earlier; right?
214:14 A. Yes.
214:15 Q. And for a life test to be a success, the
214:16 instrument has to operate according to specifications;
214:17 right?
214:18 A. Yes.
214:19 Q. And so for an instrument to meet its 10 uses,
214:20 it would have to operate according to those
214:21 specification for all ten uses; right?
214:22 A. You'd have to statistically justify ten uses
214:23 so you have to test it beyond ten uses, but yes.
214:24 Q. Now, in the process of testing, if scissors
214:25 on a pair of EndoWrist that have scissors at the end
215:01 become dull and they're no longer cutting, that would
215:02 be a failure; right?
215:03 A. Yes.
215:04 Q. And that could occur at nine uses; right?
215:05 A. Yes.
215:06 Q. Could occur at five uses; right?
215:07 A. Well, the failure could occur at any number.
215:08 That would fail the test, and we wouldn't
215:09 commercialize that product if it was during our life
215:10 testing.
215:11 Q. Well, in fact, Intuitive is aware that some
215:12 products do, in fact, fail in the market before their
215:13 use counter has expired; right?
215:14 A. Yes.
215:15 Q. Now, my question is just about the initial
215:16 testing process.
215:17 If an instrument fails because its scissors
215:18 are dull at, let's say, eight uses, does Intuitive try
215:19 to resharpen or in any way repair the scissors to
215:20 determine whether the instrument can last for
215:21 additional lives?
215:22 A. No, I don't believe so. We don't typically

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	215:23 do repairs as part of our life testing. 215:24 Q. And so if an instrument failed at, say, eight 215:25 uses because the scissors were dull, Intuitive would 216:01 consider that a failure under its life testing; right? 216:02 A. Yes. 216:03 Q. Intuitive would log that and store or dispose 216:04 of the instrument; right? 216:05 A. Yes. 216:06 Q. Intuitive would not test whether the 216:07 instrument could continue to operate to 15 or 20 uses 216:08 with re-sharpened scissors; right? 216:09 A. Not if our spec was ten and there was a 216:10 failure prior to ten, no. 216:11 Q. In fact, in -- if an instrument -- withdrawn. 216:12 And that's the same for -- for other types of 216:13 instruments as well, such as graspers or needle 216:14 drivers; right? If there's any sort of failure, 216:15 Intuitive doesn't attempt to repair that failure; 216:16 right? 216:17 A. Correct. As part of our life testing 216:18 remanufacturing, it's not part of our life testing. 216:19 Q. In fact, any sort of refurbishing repair is 216:20 not part of life testing; right? 216:21 A. Correct. 216:22 Q. Now, if an instrument -- the desired spec for 216:23 an instrument is ten uses and the instrument fails at 216:24 11 uses, Intuitive doesn't also attempt any 216:25 refurbishment or repair of that instrument at that 217:01 point; right? 217:02 A. Correct. 217:03 Q. So if an instrument, for example, failed at 217:04 11 uses because the scissors had dulled, Intuitive 217:05 would not examine whether a repair could let that 217:06 instrument operate safely; right? 217:07 A. Not typically, no.		
226:23 - 226:25	**DeSantis, Mr Bob 2021-05-27**	00:00:13	**V1M.35**
	226:23 Q. I want to shift gears with you a little bit, 226:24 Mr. DeSantis, and talk about studies that Intuitive 226:25 has done in refurbishing and repairing EndoWrists.		
227:02 - 227:04	**DeSantis, Mr Bob 2021-05-27**	00:00:10	**V1M.36**

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	227:02 I understand that in 2017 Intuitive		**V1M.36**
	227:03 considered refurbishing EndoWrists; is that right?		
	227:04 A. Yes.		
242:24 - 243:08	**DeSantis, Mr Bob 2021-05-27**	00:00:50	**V1M.56**
	242:24 Q. At any point since 2017, has Intuitive, in		
	242:25 fact, implemented a refurbishment program?		
	243:01 A. No, we have not.		
	243:02 Q. Why not?		
	243:03 A. We determined that the cost to produce		
	243:04 remanufactured instruments at the specs and quality		
	243:05 levels of a new instrument would be too close to the		
	243:06 cost of just manufacturing new instruments with all		
	243:07 new parts. So financially it didn't -- we weren't		
	243:08 motivated to develop and implement the program.		
243:13 - 244:14	**DeSantis, Mr Bob 2021-05-27**	00:01:52	**V1M.74**
	243:13 Q. One of the objectives of Project Dragon was		
	243:14 to increase entry barriers for third-party		
	243:15 re-programming of EndoWrist; true?		
	243:16 A. It was a -- it was a lower-level		
	243:17 consideration. You know, so we were looking at		
	243:18 primarily being able to offer reduced costs to the		
	243:19 customers. And then there were a couple of secondary		
	243:20 considerations. One of them was reducing waste into		
	243:21 the environment. And the other one was, you know,		
	243:22 protecting our brand and our quality from, you know,		
	243:23 third parties who are remanufacturing adulterating		
	243:24 instruments not to our specs.		
	243:25 Q. Well, sir, how did you know a third party is		
	244:01 not refurbishing to Intuitive's specifications?		
	244:02 You haven't tested the instrument; right?		
	244:03 A. So two different questions.		
	244:04 We have not done V&V testing on a third		
	244:05 party. But our -- our specifications and our		
	244:06 requirements are our intellectual property of the		
	244:07 company which we've not released. So I don't know how		
	244:08 a third party would be able to ensure and guarantee		
	244:09 that their quality system -- that they were developing		
	244:10 to our specs, that their quality system was sufficient		
	244:11 and on par with us, et cetera, et cetera.		
	244:12 That's really, you know, a lot of the		

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	244:13 investment that we've put in the -- into the company 244:14 to develop those specific types of things.		
244:16 - 244:23	**DeSantis, Mr Bob 2021-05-27**	00:00:24	**V1M.37**
	244:16 Intuitive has not performed any sort of 244:17 testing of third-party instruments that would -- 244:18 withdrawn. 244:19 Intuitive has not performed any instruments 244:20 refurbished by Rebotix to determine whether or not 244:21 they perform to in Intuitive's specifications; right? 244:22 A. We have not done V&V or life testing on their 244:23 instruments, no.		
245:06 - 245:11	**DeSantis, Mr Bob 2021-05-27**	00:00:27	**V1M.38**
	245:06 Intuitive has not done testing of any kind to 245:07 determine whether Rebotix's refurbished EndoWrists can 245:08 safely be used with the da Vinci robot in surgery; 245:09 true? 245:10 A. True. We've not done V&V testing, life 245:11 testing on their instruments, no.		
249:18 - 249:22	**DeSantis, Mr Bob 2021-05-27**	00:00:15	**V1M.39**
	249:18 Q. Well, based on the cost of goods for a new 249:19 EndoWrist, is it your understanding that the margin 249:20 for a new EndoWrist is about 89 percent? 249:21 A. Right, right in that ballpark, yes. That's 249:22 the contribution margin.		
256:08 - 256:15	**DeSantis, Mr Bob 2021-05-27**	00:00:35	**V1M.57**
	256:08 Q. A refurbished product offering would allow 256:09 for more cost-conscious customers to potentially gain 256:10 access to the da Vinci robot in the EndoWrist; right? 256:11 A. Not according to our tests. Because a 256:12 refurbished program didn't equate to a reduced cost 256:13 for us. I would -- I would say that a lower cost per 256:14 use has the potential which we don't have any proof 256:15 yet to provide more access in the marketplace.		
266:01 - 266:10	**DeSantis, Mr Bob 2021-05-27**	00:00:37	**V1M.58**
	266:01 Now, ultimately Intuitive did not pursue an 266:02 instrument refurbishment program for the da Vinci Si 266:03 or for the da Vinci Xi; right? 266:04 A. Not to date. 266:05 Q. It's because instrument refurbishing, that's		

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	266:06 something that's not profitable for Intuitive; right? 266:07 A. Yeah. Financially it turned out to be 266:08 essentially a wash between building new instruments 266:09 and going through the entire process of collecting and 266:10 remanufacturing to original specs, et cetera.		
267:19 - 268:04	**DeSantis, Mr Bob 2021-05-27**	00:00:32	**V1M.40**
	267:19 Q. When you say you informed the hospitals, one 267:20 of the things that you've told the hospitals was that 267:21 Intuitive would cancel the sales contract with the 267:22 hospitals if they continued using services like 267:23 Rebotix; right? 267:24 A. That was usually a third or fourth step. Our 267:25 first was just to inform them and clarify, because 268:01 there was a lot of confusion out there that this was 268:02 not authorized, and we did not have a relationship 268:03 with Rebotix, and there was a bunch of other 268:04 confusions but-		
268:07 - 269:03	**DeSantis, Mr Bob 2021-05-27**	00:01:00	**V1M.41**
	268:07 THE WITNESS: First it was to have a 268:08 conversation just clarifying the -- the facts of the 268:09 matter. 268:10 MR. ERWIG: Q: And the letter that was sent 268:11 to hospitals, you're aware that that included a 268:12 section about the hospitals being in breach of the 268:13 contract with Intuitive; right? 268:14 A. I believe so. But the letter was not our 268:15 first step. 268:16 Q. Right. 268:17 A. first step would be a conversation with a 268:18 hospital; right? 268:19 A Yes. 268:20 Q. And if the hospital continued using Rebotix, 268:21 then Intuitive would send a letter; right? 268:22 A. We laid out a multistep process that would 268:23 eventually get to the point where we didn't want to 268:24 get to. But again, to defend the reputation of the 268:25 company and our platform. Then again, if the hospital 269:01 continued to use something that we felt was 269:02 unauthorized, unsafe, we would terminate our 269:03 relationship with the hospital.		

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269:13 - 269:17	**DeSantis, Mr Bob 2021-05-27**	00:00:20	**V1M.59**
	269:13 Was Intuitive ever able to provide any data 269:14 that indicated that EndoWrists refurbished by Rebotix 269:15 were unsafe? 269:16 A. So don't we have Rebotix's testing protocols, 269:17 life testing, quality system, returns.		
269:18 - 269:21	**DeSantis, Mr Bob 2021-05-27**	00:00:09	**V1M.60**
	269:18 We don't have any of that data. 269:19 The data we have is the testing we've done 269:20 and why we had indicated ten lives, et cetera and that 269:21 we certainly have provided.		
270:07 - 270:10	**DeSantis, Mr Bob 2021-05-27**	00:00:21	**V1M.42**
	270:07 Q. Intuitive did not provide any data about the 270:08 safety of Rebotix's refurbished EndoWrists; right? 270:09 A. I don't believe so. We're not in a position 270:10 to provide Rebotix's data.		
270:11 - 270:19	**DeSantis, Mr Bob 2021-05-27**	00:00:27	**V1M.61**
	270:11 Q. Well, one -- one thing that Intuitive could 270:12 have done would be to take an EndoWrist that was 270:13 refurbished by Rebotix and see whether it meets the 270:14 specs set by Intuitive; right? 270:15 A. That would really be meaningless on a one-off 270:16 basis. We would -- to properly conduct V&V testing 270:17 there's a lot of requirements that -- that are 270:18 involved, and it's more than just taking one 270:19 instrument and testing it.		
271:02 - 271:14	**DeSantis, Mr Bob 2021-05-27**	00:00:42	**V1M.62**
	271:02 MR. ERWIG: Q: Well, one thing that would be 271:03 meaningful would be for Intuitive to have an actual 271:04 sense of whether the instruments refurbished by 271:05 Rebotix, whether those were safe; right? 271:06 A. Intuitive has 20 years and millions of 271:07 procedures of instrument experience that -- you know, 271:08 that we -- we know that what we do is safe, and we 271:09 have a lot of information about ten lives, and quality 271:10 levels, and the complaints, et cetera. 271:11 So, you know, if -- I believe when we're 271:12 dealing with humans, and people and patients, that the 271:13 onus is on, you know, the company providing to ensure		

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	271:14 that they're safe.		
271:25 - 272:14	**DeSantis, Mr Bob 2021-05-27**	00:00:48	**V1M.63**
	271:25 Intuitive has no data on the safety of 272:01 repairs of EndoWrists; true? 272:02 A. No. I think we're talking past each other a 272:03 little bit on -- you know, we -- we have a lot of data 272:04 on how these instruments wear down, how they fail, 272:05 what they look like after ten lives. It's why we 272:06 chose to do what we want, what we -- what we did on 272:07 Project Dragon which was it throw out things like 272:08 cables and grips that are the highest failure modes 272:09 based on lots and lots of data. 272:10 And, you know, for us to look across it, at 272:11 somebody else doing that -- so anyway, we made our 272:12 decisions on our programs based on our judgment, based 272:13 on our specs, based on our history. And we feel good 272:14 about that.		
272:15 - 273:24	**DeSantis, Mr Bob 2021-05-27**	00:02:06	**V1M.64**
	272:15 Q. And then the span of that time and 272:16 experience, one of the areas that Intuitive did not 272:17 explore was whether it was possible to repair an 272:18 EndoWrist where, for example, the cables had become 272:19 loose; right? 272:20 A. We know exactly how cables perform over time. 272:21 And when cables become loose, there's a lot of things 272:22 going on there that are dangerous. So no, we have not 272:23 tried to repair loose cables. 272:24 Q. Another thing that might be an issue with an 272:25 EndoWrist would be misaligning graspers; right? 273:01 A. Could be, yes. 273:02 Q. Has Intuitive ever examined whether it's 273:03 possible to repair misaligned graspers? 273:04 A. It's the same type of answer. The failure of 273:05 the grips is one of our highest failure modes. They 273:06 fail usually because they break. They break of a 273:07 brittle failure. 273:08 Realigning graspers means that you are 273:09 bending back into shape typically, which means you're 273:10 taking them past their yield point which makes them 273:11 more brittle, which would add to our failure rate. So		

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	273:12 no, we haven't.		
	273:13 Q. Another potential failure might be the		
	273:14 scissors, even if they're German-manufactured		
	273:15 scissors, those might get dull; right?		
	273:16 A. Yes.		
	273:17 Q. Has Intuitive ever tested whether it's		
	273:18 possible to repair those scissors by sharpening them		
	273:19 so they cut effectively?		
	273:20 A. So scissor performance is more than just the		
	273:21 blade. It's the sharpness, it's the hardness, it's		
	273:22 the contact angle. So the cost involved in doing that		
	273:23 is -- for us did not justify the need to do the --		
	273:24 the -- you know, the -- the plan to resharpen them.		
276:16 - 277:02	**DeSantis, Mr Bob 2021-05-27**	00:00:42	**V1M.65**
	276:16 A. And so everything we've talked about and we		
	276:17 do would require that we bring things back to at least		
	276:18 our original specs. We're not going to -- we're not		
	276:19 going to compromise on quality or performance when it		
	276:20 comes to people.		
	276:21 What we know is bending parts back into shape		
	276:22 or reusing cables that have stretched and started to		
	276:23 fray will -- you know, again based on our engineering		
	276:24 judgment, and our experience, it is -- will not bring		
	276:25 them back to spec and will not allow them to last the		
	277:01 indicated life, and it's dangerous. They have been		
	277:02 moved closer to their failure point.		

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Designation List Report

McGrogan, Anthony **2021-06-07**

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5:23 - 7:08	**McGrogan, Anthony 2021-06-07**	00:02:04	**V1M.1**

5:23 Q. Good morning, Mr. McGrogan.
5:24 A. Good morning.
5:25 Q. Could you please state your full name for
6:01 the record.
6:02 A. Sure. It's Anthony Kelly McGrogan.
6:03 Q. And I understand that you work at Intuitive
6:04 Surgical; is that right?
6:05 A. I do.
6:06 Q. What is your position at Intuitive?
6:07 A. My title? Is that what you're asking?
6:08 Q. Yes.
6:09 A. My title is vice president -- vice
6:10 president of design engineering, single-port
6:11 platforms.
6:12 Q. And how long have you been in that
6:13 position?
6:14 A. Six months.
6:15 Q. Did you have any prior roles at Intuitive
6:16 before you came to that position?
6:17 A. I did. The prior four years, I was a vice
6:18 president of engineering for surgical instruments
6:19 and accessories.
6:20 Q. What were your responsibilities as a vice
6:21 president of engineering for instruments and
6:22 accessories?
6:23 A. Primarily overseeing the design and
6:24 development of new products for the da Vinci Xi and
6:25 SP platforms, but also the maintenance and quality
7:01 for the existing product lines.
7:02 Q. Did you have any roles at Intuitive prior
7:03 to that role?
7:04 A. Yes. So let's see. For the previous, I
7:05 guess, 11 years -- or approximately 11 years; I
7:06 guess 10 1/2 years -- I was -- I had various design
7:07 and leadership responsibilities for da Vinci SP, our
7:08 single-port platform.

7:11 - 7:13	**McGrogan, Anthony 2021-06-07**	00:00:06	**V1M.22**

7:11 Q. You understand that you're here testifying
7:12 as a 30(b)(6) witness?

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	7:13 A. I do.		
7:14 - 7:21	**McGrogan, Anthony 2021-06-07**	00:00:17	**V1M.2**
	7:14 Q. And you understand that as a 30(b)(6) 7:15 witness, you've been designated to provide testimony 7:16 on behalf of Intuitive on a number of topics? 7:17 A. Yes. 7:18 Q. You understand that for those topics that 7:19 you've been designated on, your answers are binding 7:20 on Intuitive? 7:21 A. Yes.		
8:24 - 9:11	**McGrogan, Anthony 2021-06-07**	00:00:33	**V1M.3**
	8:24 Q. You understand that you've been designated 8:25 to provide testimony on behalf of Intuitive on 9:01 Topic 12, which is Intuitive's determination of the 9:02 maximum use requirement for each EndoWrist -- 9:03 A. Yes. 9:04 Q. -- in considerations, testing, studies, or 9:05 analyses relevant to the determination. 9:06 A. Yes. 9:07 Q. Have you seen that topic before? 9:08 A. I have. 9:09 Q. Are you fully prepared to testify on behalf 9:10 of Intuitive for Topic 12 today? 9:11 A. I'm prepared to give it my best.		
15:14 - 15:20	**McGrogan, Anthony 2021-06-07**	00:00:38	**V1M.4**
	15:14 Q. And you tell me which da Vinci robot each 15:15 of those numbers corresponds to? 15:16 A. Oh. I think the IS1200 is referred to as 15:17 the standard. IS3000 -- sorry. IS2000 is referred 15:18 to as the da Vinci S. IS3000 is the da Vinci Si. 15:19 IS4000 is the da Vinci Xi. And IS4200 is the 15:20 da Vinci X.		
17:13 - 18:06	**McGrogan, Anthony 2021-06-07**	00:00:49	**V1M.5**
	17:13 Q. In what situations would a life be 17:14 subtracted from the life counter? 17:15 A. If you install an instrument and you insert 17:16 it into the body and it goes in to follow, like 17:17 meaning a surgeon takes control of it and starts to 17:18 manipulate tissue, then it will -- in that case, it		

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	17:19 will subtract a use. 17:20 Q. And it will subtract that use regardless of 17:21 the amount of time that the instrument is used in 17:22 the body; is that right? 17:23 A. Yes. 17:24 Q. So if a surgeon used an instrument for, 17:25 let's say, ten seconds inside a patient's body, that 18:01 would subtract a use; right? 18:02 A. That's right. 18:03 Q. If a surgeon used an instrument for two 18:04 hours inside a patient's body, that would also 18:05 subtract one use or one life; right? 18:06 A. That's right.		
24:11 - 26:25	**McGrogan, Anthony 2021-06-07**	00:02:49	**V1M.6**
	24:11 Q. Might have a very short surgery where 24:12 EndoWrists are used for a few seconds or a few 24:13 minutes; right? 24:14 A. Yes. 24:15 Q. You might have other longer surgeries where 24:16 EndoWrists are used for an hour or two hours; right? 24:17 A. Yes. 24:18 Q. And in each of those instances, after the 24:19 surgery is complete, the EndoWrist would decrement a 24:20 life from the life counter; right? 24:21 A. Yes. At a high level, that's true. Again, 24:22 I don't know the details of the algorithm. But at a 24:23 high level, yes. 24:24 Q. Now, let's assume that there is one 24:25 instrument that's used ten times for about an hour 25:01 per surgery. 25:02 Okay? Are you with me? 25:03 A. Yep. 25:04 Q. That instrument, according to Intuitive, is 25:05 safe to be used for ten uses; right? 25:06 A. Yes. 25:07 Q. After those ten uses are up, Intuitive 25:08 would tell the hospital you need to throw this 25:09 instrument away; right? 25:10 A. Right. 25:11 Q. Now, let's take another instrument, same		

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	25:12	instrument. Let's use a cold grasper. It's used		
	25:13	for one minute during surgery at different times.		
	25:14	A. M-hm.		
	25:15	Q. Was that a 'yes'?		
	25:16	A. Yes.		
	25:17	Q. Intuitive would also tell the hospital to		
	25:18	throw that instrument away after ten uses; right?		
	25:19	A. Yes.		
	25:20	Q. So the first instrument would have been		
	25:21	used actually in surgery for ten hours; right?		
	25:22	A. M-hm.		
	25:23	Q. 'Yes'?		
	25:24	A. The total surgical time is, I believe,		
	25:25	ten -- yes, ten hours.		
	26:01	Q. The second instrument would have been used		
	26:02	in surgery for ten minutes; right?		
	26:03	A. Yes.		
	26:04	Q. Intuitive would tell hospitals that each		
	26:05	one of those instruments needs to be thrown away;		
	26:06	right?		
	26:07	A. That's true.		
	26:08	Q. Now, the instrument that's been used in		
	26:09	surgery for ten minutes, that instrument could		
	26:10	safely be used for surgery much longer than that;		
	26:11	right?		
	26:12	A. Well, it depends on what it did over those		
	26:13	ten minutes.		
	26:14	Just like the instrument that was used for		
	26:15	an hour, if you put an instrument in for an hour and		
	26:16	you just grab some tissue and retract and you just		
	26:17	leave it retracting, say, the liver for 50 minutes,		
	26:18	it's just gripped once.		
	26:19	But that instrument that was put in for one		
	26:20	minute could have done some detailed anastomosis		
	26:21	through some really tough tissue and grabbed a bunch		
	26:22	of needles.		
	26:23	And so it's difficult, just using the		
	26:24	metric of time, to determine how much wear you put		
	26:25	on the instrument.		
27:01 - 27:19	**McGrogan, Anthony 2021-06-07**		00:01:09	**V1M.23**

DESIGNATION	SOURCE	DURATION	ID
	27:01 Q. You used a specific technical term that I 27:02 would like to just use as an example. Can you say 27:03 that for me one more time that you -- you said a 27:04 difficult anastomosis? 27:05 A. Anastomosis. You're sewing up a vessel or 27:06 you're -- you're bridging -- it's a surgical term, 27:07 but -- it's a suturing term. 27:08 Q. When you say 'suturing,' what do you -- 27:09 what do you mean by that? 27:10 A. Suturing, sewing, using an instrument to 27:11 push a needle through tissue and tie knots. So 27:12 typically very hard on an instrument. 27:13 Q. You mentioned that you might not be able to 27:14 compare an instrument that's been used for that 27:15 complex process of sewing to an instrument that's 27:16 only been used to grab and hold tissue in one space? 27:17 A. Right. I'm saying that the metric of time 27:18 to determine the use and wear on an instrument is 27:19 not a good metric.		**V1M.23**
28:21 - 28:25	**McGrogan, Anthony 2021-06-07** 28:21 Q. The hospital isn't, for example, required 28:22 to say 'I used this instrument for a simple 28:23 procedure. I used this instrument for a complex 28:24 procedure,' or anything like that; right? 28:25 A. They are not.	00:00:12	**V1M.7**
32:09 - 32:22	**McGrogan, Anthony 2021-06-07** 32:09 Q. Well, one way that Intuitive could measure 32:10 the life left in an instrument would be to measure 32:11 the instrument based on the time that it's been used 32:12 in surgery; right? 32:13 A. I think we talked that time is not a good 32:14 metric for measuring wear and tear. 32:15 Q. Well, the time takes into account how -- 32:16 how long an instrument has been used in a given 32:17 procedure; right? 32:18 A. That's all it takes into account. 32:19 Q. Another thing that you might want to take 32:20 into account would be the complexity of what the 32:21 instrument is being used for right? 32:22 A. That's right.	00:00:39	**V1M.8**

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33:01 - 33:17	**McGrogan, Anthony 2021-06-07**	00:00:44	**V1M.9**

33:01 BY MR. ERWIG:
33:02 Q. I'm sorry. I didn't get your answer.
33:03 A. I said yes.
33:04 Q. Now, a decrementing of the life on a use
33:05 counter, that doesn't take into account either the
33:06 time that the instrument has been used in surgery or
33:07 the complexity of what the instrument did during the
33:08 surgery; right?
33:09 A. That's right, as far as I know.
33:10 Again, I don't know the details of the
33:11 algorithm. But, generally speaking, if you use it
33:12 in surgery, it's going to get decremented.
33:13 Q. That's the same whether it's been used for
33:14 ten simple short procedures or ten --
33:15 A. Yes --
33:16 Q. -- complex, long procedures; right?
33:17 A. Yes, yes.

35:05 - 35:20	**McGrogan, Anthony 2021-06-07**	00:00:51	**V1M.10**

35:05 I want to talk to you a little bit how the
35:06 life counter's original lives for instruments are
35:07 originally set. Okay?
35:08 A. Okay.
35:09 Q. Now, when Intuitive is first considering
35:10 what it's going to be setting the lives at,
35:11 marketing is involved in that process; right?
35:12 A. Marketing is involved to the extent that
35:13 they set goals for engineering.
35:14 Q. For example, marketing might set a goal of
35:15 ten lives for an instrument; right?
35:16 A. That's an example, yes.
35:17 Q. And then engineering would try to design an
35:18 instrument that would meet that ten-life goal;
35:19 right?
35:20 A. Yes.

35:21 - 36:12	**McGrogan, Anthony 2021-06-07**	00:01:25	**V1M.24**

35:21 Q. Now, if the instrument, in fact, exceeded
35:22 that ten-life goal, then marketing would have to be
35:23 involved to see whether the life limit should be
35:24 pushed higher; right?

DESIGNATION	SOURCE	DURATION	ID
	35:25 A. I can't think of an example where that's 36:01 actually happened, so I will have to say that I 36:02 don't really know what would happen in that case. 36:03 Q. You can't think of an example where an 36:04 instrument exceeded the marketing target and then 36:05 marketing was consulted whether the instrument's 36:06 lives should be increased? 36:07 A. I know there are examples where we have 36:08 exceeded the targets and engineering was consulted 36:09 on what the target -- the final target should be. 36:10 But I'm not aware of us exceeding it and asking 36:11 marketing's opinion on the number. We've only -- 36:12 we've rarely exceeded it.		
36:15 - 36:16	**McGrogan, Anthony 2021-06-07** 36:15 When marketing initially sets the target 36:16 number of lives, how is that process performed?	00:00:06	**V1M.11**
36:17 - 36:23	**McGrogan, Anthony 2021-06-07** 36:17 A. I guess it's done -- over the years I've 36:18 been at Intuitive, it's been done in different ways. 36:19 Typically, they -- they give us a goal. It 36:20 can be in the form of a specification document or a 36:21 product requirements document or a marketing 36:22 requirements document. Or it can just be through 36:23 e-mails, informal.	00:00:24	**V1M.12**
36:24 - 37:06	**McGrogan, Anthony 2021-06-07** 36:24 Q. And that goal, how is -- how is that 36:25 determined? 37:01 A. The marketing goal, you're asking about? 37:02 Q. Correct. 37:03 A. I'm not sure. In the cases that -- in the 37:04 cases that -- you know, in the examples that I've 37:05 been involved in, engineering helps set that target, 37:06 but I'm not certain in all cases how it's been done.	00:00:35	**V1M.25**
37:07 - 38:08	**McGrogan, Anthony 2021-06-07** 37:07 Q. Well, marketing could, for example, send an 37:08 e-mail that said, hey, we have a goal of five lives; 37:09 right? 37:10 A. Sure. 37:11 Q. And then engineering would try to design a	00:01:20	**V1M.26**

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	37:12 product that would meet that particular 37:13 specification; right? 37:14 A. It could. It's a little more complicated 37:15 than that. 37:16 Q. Well, what additional level of complexity 37:17 am I missing? 37:18 A. The cost of the instrument, the business 37:19 case. There's other factors that go into it. 37:20 Q. When you say 'the business case,' you mean 37:21 the revenue from selling instruments with particular 37:22 lives? 37:23 A. Or in my case, I don't deal with revenue, 37:24 per se, but I just deal with cost, what it costs to 37:25 make an instrument. 38:01 Q. And the actual revenue calculations, those 38:02 are -- that's marketing's role? 38:03 A. Finance's role, typically. 38:04 Q. Finance could, for example, determine 38:05 whether it's more profitable to set the lives of an 38:06 instrument at five or at ten; right? 38:07 A. Finance doesn't make that kind of 38:08 determination. I'm just saying that there are --		
38:09 - 38:14	**McGrogan, Anthony 2021-06-07**	00:00:33	**V1M.27**
	38:09 there are cases where if the use is not high enough 38:10 that it just -- we couldn't really make the 38:11 instrument and be profitable. So it has to be high. 38:12 Like, they're pushing the -- the life number up, not 38:13 down, I guess is what I'm saying. They set higher 38:14 goals for us, not lower ones.		
54:10 - 54:14	**McGrogan, Anthony 2021-06-07**	00:00:15	**V1M.28**
	54:10 Q. Does the actual reprocessing cycle place 54:11 strain on the cables within the EndoWrist 54:12 instruments? 54:13 A. It greatly -- or it significantly degrades 54:14 the instrument.		
54:17 - 54:25	**McGrogan, Anthony 2021-06-07**	00:00:32	**V1M.13**
	54:17 The -- the actual cables inside of the 54:18 EndoWrist instruments, are those degraded in the 54:19 process of cleaning and sterilization? 54:20 A. Yes.		

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	54:21 Q. How? 54:22 A. I can't say that we understand it all the 54:23 way down to the molecular level. But at the end of 54:24 the day, the reprocessing seems to relax the cables 54:25 slowly in the instrument.		
55:01 - 55:08	**McGrogan, Anthony 2021-06-07**	00:00:35	**V1M.29**
	55:01 Q. In other words, you'd have to check and 55:02 make sure that the cables were sufficiently tight 55:03 after a reprocessing cycle; right? 55:04 A. Well, an end user can't really do that, but 55:05 we can do that with our machines in the factory 55:06 to -- and it's something we note -- or have noted in 55:07 engineering in studying how the instruments are 55:08 impacted by the reprocessing.		
55:09 - 55:12	**McGrogan, Anthony 2021-06-07**	00:00:10	**V1M.14**
	55:09 Q. Intuitive has not, though, for example, 55:10 tested whether it's possible to tighten the cables 55:11 after they've been relaxed in a reprocessing cycle; 55:12 right?		
55:16 - 55:24	**McGrogan, Anthony 2021-06-07**	00:00:31	**V1M.15**
	55:16 THE WITNESS: A customer can't tighten the 55:17 cables. But Intuitive, in engineering, has the 55:18 ability to do that. 55:19 BY MR. ERWIG: 55:20 Q. And has Intuitive tested, in its 55:21 engineering program, whether it's possible to 55:22 tighten cables after they've been relaxed through 55:23 reprocessing cycles? 55:24 A. I'm not sure.		
55:25 - 56:02	**McGrogan, Anthony 2021-06-07**	00:00:08	**V1M.30**
	55:25 Q. Is there any indication that it's not 56:01 possible to tighten the cables after they've been 56:02 relaxed in a reprocessing cycle?		
56:03 - 56:03	**McGrogan, Anthony 2021-06-07**	00:00:02	**V1M.31**
	56:03 A. I'm not sure.		
59:02 - 59:08	**McGrogan, Anthony 2021-06-07**	00:00:22	**V1M.32**
	59:02 In some instances, the engineering team 59:03 might suggest a higher number of lives, and 59:04 marketing might not agree to that higher number of		

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	59:05 lives; right? 59:06 A. That's -- that's very hypothetical and 59:07 highly unlikely, and I've never seen that happen 59:08 before.		
59:09 - 59:15	**McGrogan, Anthony 2021-06-07**	00:00:18	**V1M.16**
	59:09 Q. Well, there's certainly been instances 59:10 where the instrument being tested passed more lives 59:11 than were actually implemented; right? 59:12 A. Yes. 59:13 Q. Now, the instrument could have been set at 59:14 a higher number of lives; right? 59:15 A. Yes.		
62:10 - 62:16	**McGrogan, Anthony 2021-06-07**	00:00:17	**V1M.17**
	62:10 Q. There's certainly some instances where the 62:11 number of lives implemented is different from the 62:12 number of lives proven; right? 62:13 A. Yes. 62:14 Q. And the number of lives implemented, those 62:15 are less than the lives proven; right? 62:16 A. Yes, in some cases.		
64:01 - 64:04	**McGrogan, Anthony 2021-06-07**	00:00:13	**V1M.33**
	64:01 Q. It's not the case that the instruments are 64:02 first tested to determine their maximum number of 64:03 lives; right? 64:04 A. Well, we do informal testing all the time.		
64:05 - 64:08	**McGrogan, Anthony 2021-06-07**	00:00:09	**V1M.18**
	64:05 Q. But when a new instrument is being 64:06 developed for a customer, marketing is setting the 64:07 target for that instrument before there's any 64:08 testing that's conducted; right?		
64:14 - 64:19	**McGrogan, Anthony 2021-06-07**	00:00:17	**V1M.19**
	64:14 THE WITNESS: Marketing sets a goal for 64:15 reposable instruments. 64:16 BY MR. ERWIG: 64:17 Q. Then engineering designs and tests an 64:18 instrument to try to achieve that goal; right? 64:19 A. That's right.		
64:20 - 64:23	**McGrogan, Anthony 2021-06-07**	00:00:12	**V1M.34**
	64:20 Q. It's not that case that every instrument,		

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	64:21 for example, that's developed by engineering is 64:22 tested to failure to see what the absolute maximum 64:23 number of uses for it is; right?		
65:03 - 65:05	**McGrogan, Anthony 2021-06-07**	00:00:13	**V1M.35**
	65:03 THE WITNESS: There's all sorts of informal 65:04 testing that's done to establish the final number of 65:05 uses that we label an instrument with.		
65:09 - 65:12	**McGrogan, Anthony 2021-06-07**	00:00:18	**V1M.36**
	65:09 Q. Now, the informal testing is performed 65:10 after the initial target use number has been set by 65:11 marketing for a particular instrument; right? 65:12 A. It could be before; it could be after.		
65:19 - 65:25	**McGrogan, Anthony 2021-06-07**	00:00:21	**V1M.20**
	65:19 Q. Now, for formal life testing, formal life 65:20 testing is performed after there's been a particular 65:21 target set by marketing; right? 65:22 A. Typically, yes, formal life testing. 65:23 Q. That's ultimately what's used when 65:24 Intuitive sets the life counter; right? 65:25 A. Yes.		
77:12 - 77:23	**McGrogan, Anthony 2021-06-07**	00:00:49	**V1M.21**
	77:12 The da Vinci Si and Xi, are there any 77:13 changes between the use counter on those two 77:14 instruments in terms of the actual design of the use 77:15 counter, not the lives? 77:16 A. Yes. 77:17 Q. What change? 77:18 A. The Gen 3 Si/S instruments, those use a 77:19 Dallas chip, which is a hard-wire connection. And 77:20 on Gen 4, which is X/Xi, we use an RFID counter. 77:21 Q. Any other changes in the use counter other 77:22 than that? 77:23 A. Those are the primary changes.		
81:04 - 81:10	**McGrogan, Anthony 2021-06-07**	00:00:25	**V1M.37**
	81:04 Q. As you use the term 'informal testing,' 81:05 what does that mean? 81:06 A. So we -- informal testing is testing that 81:07 engineering does to understand our products, 81:08 understand their failure modes, understand, you		

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	81:09	know, how they work and how they behave so that we	
	81:10	can make them better and evolve them.	